

**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, 2021
- 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 001-40657

**Omega Therapeutics, Inc.**  
(Exact name of Registrant as specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20 Acorn Park Drive  
Cambridge, MA**  
(Address of principal executive offices)

**81-3247585**  
(I.R.S. Employer  
Identification No.)

**02140**  
(Zip Code)

Registrant's telephone number, including area code: (617) 949-4360

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, par value \$0.001 per share	OMGA	The Nasdaq Global Select Market

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 Exchange Act). YES  NO

The Registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

The number of shares of Registrant's Common Stock outstanding as of March 4, 2022 was 47,807,651.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2022 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2021, are incorporated herein by reference in Part III.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, product candidate development, prospective products, product candidate approvals, research and development activities and costs, future revenue, timing and likelihood of success of our business plans, plans and objectives of management, future results and timing of clinical trials, treatment potential of our product candidates, and the market potential of our product candidates are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "would" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this Annual Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under Part I, Item 1A. "Risk Factors" in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

As used in this Annual Report, unless otherwise stated or the context requires otherwise, references to "Omega," "Omega Therapeutics," the "Company," "we," "us," and "our," refer to Omega Therapeutics, Inc. and its subsidiary on a consolidated basis.

## SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of preclinical and clinical development and of subsequently obtaining regulatory approval, if at all.
- No epigenomic controller medicines have been approved in this potentially new class of medicines, and may never be approved as a result of efforts by others or us. mRNA drug development has substantial development and regulatory risks due to the novel and unprecedented nature of this new category of medicines.
- We have a limited operating history and no history of successfully developing or commercializing any approved product candidates, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.
- We have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future.
- We require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce, or terminate our product development.
- We have invested, and expect to continue to invest, in research and development efforts that further enhance the OMEGA Epigenomic Programming platform. Such investments may affect our operating results, and, if the return on these investments is lower or develops more slowly than we expect, our revenue and operating results may suffer.
- Preclinical development is uncertain, especially for a new class of medicines such as epigenomic controllers, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance into the clinic, any of which may have a material adverse impact on our platform or our business.
- Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.
- Due to increased demand for the manufacture of mRNA- and LNP-based vaccines to treat COVID-19, our ability to manufacture our Omega Epigenomic Controller candidates, or OEC candidates, for preclinical or clinical supply could be limited, which could adversely affect our development plans.
- Our OEC candidates are based on novel technology and may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping.
- We must adapt to rapid and significant technological change and respond to introductions of new products and technologies by competitors to remain competitive.
- We will rely on third parties for the foreseeable future for the manufacture of materials for our research programs, preclinical studies and clinical trials and we do not have long-term contracts with many of these parties. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies 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 are planning to acquire and establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on contract development and manufacturing organizations for the manufacture of our product candidates, which will be costly, time-consuming, and which may not be successful.
- We have a limited number of suppliers for the lipid excipients used in our product candidates and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our product candidates. If we

obtain regulatory approval for any of our product candidates, we would need to expand the supply of lipid excipients in order to commercialize them.

- We are very early in our development efforts. All of our product candidates are in preclinical development or discovery and it will be many years before we commercialize a product candidate, if ever. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- If we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

## Item 1. Business.

## Overview

Omega Therapeutics is pioneering a systematic approach to use mRNA therapeutics as programmable epigenetic medicines by leveraging our OMEGA Epigenomic Programming platform (“OMEGA platform”). mRNA refers to Messenger RNA, a single-stranded RNA (ribonucleic acid that carries instructions for the synthesis of proteins) corresponding to the sequence of a gene. Our OMEGA platform harnesses the power of epigenetics, the mechanism that controls gene expression and every aspect of an organism's life from cell genesis, growth and differentiation to cell death. We have deciphered the three-dimensional architecture of the human genome. Genes and their accompanying regulators are organized into distinct and evolutionarily conserved structures called Insulated Genomic Domains, or IGDs. IGDs are the fundamental structural and functional units of gene control and cell differentiation and act as the “control room” of biology. Most diseases are caused by aberrant gene expression rooted in alterations in IGDs. The OMEGA platform has enabled us to systematically identify and validate thousands of novel DNA-sequence-based epigenomic “zip codes” associated with individual regulatory elements within IGDs. We call these epigenomic targets EpiZips. We rationally design and engineer our mRNA therapeutics, which are programmable and modular epigenetic medicines, called Omega Epigenomic Controllers, or OECs, to target EpiZips for Precision Genomic Control. This enables us to precisely tune genes to a desired level of expression and to control the duration of expression. Through this approach, we believe that the OMEGA platform has broad potential applicability across a range of diseases and conditions. Our pipeline currently consists of early-stage, preclinical programs that span oncology, multigenic diseases including immunology, regenerative medicine, and select monogenic diseases. We have conducted *in vivo* preclinical studies of our OECs in multiple disease models for various indications, including hepatocellular carcinoma, or HCC, non-small cell lung cancer, or NSCLC, and acute respiratory distress syndrome, or ARDS, and we expect to conduct *in vivo* preclinical studies for multiple additional programs. We initiated investigational new drug application (“IND”) enabling studies for multiple programs in 2021, and we are aiming to submit an IND for our OEC candidate for the treatment of HCC and declare two OEC development candidates in the first half of 2022. We are also planning to submit an IND for another OEC candidate in the second half of 2022 or early 2023.

The OMEGA platform consists of four pillars:

1. **Proprietary Database of IGDs and EpiZips.** Thousands of novel DNA-sequence-based epigenomic targets covering over 90% of human IGDs, identified through proprietary algorithms and machine-learning tools mining our own and public databases.
2. **Programmable and Modular Epigenetic mRNA Medicines (OECs).** Engineered and modular mRNA-encoded medicines with a DNA-binding domain to target a specific EpiZip and an effector protein to up- or down-regulate gene expression and control the duration of expression.
3. **Engineered, Customized Drug Delivery.** Lipid-nanoparticle, or LNP, delivery technology validated in third-party clinical trials. Deep formulation expertise to engineer and customize technological improvements. Continued innovation in other emerging technologies.
4. **Industry-Leading Expertise.** Codified learnings and insights gleaned from lead programs to continue optimizing the platform and inform the discovery and development of subsequent product candidates. Continued additions to the knowledge bank of EpiZips and OECs.

These pillars are supported by our deep and growing expertise in cutting-edge computational techniques, machine learning, and proprietary algorithms and a world-class and talented team. These foundations enable us to achieve data-driven decision-making, new scientific insights into complex biology, and the acceleration of engineered solutions in drug development.

We believe that the OMEGA platform has the following advantages:

- First systematic use of mRNA therapeutics as programmable epigenetic medicines.
- Thousands of novel therapeutic targets, EpiZips, across IGDs ubiquitous in every cell.

- Highly specific targeting of EpiZips.
- Precision genomic control with tunable and durable effect with the potential to re-dose.
- Single and/or multiple gene control with a single therapeutic.
- Ability to multiplex within or across IGDs for synergistic effect.
- No changes in nucleic acid sequences.
- Ability to accelerate numerous programs in parallel with real-time, data-driven decision-making.

We believe that the Precision Genomic Control delivered by the OMEGA platform has broad therapeutic applicability and transformational potential, initially spanning across:

- **Oncology.** Control of target oncogenes including historically challenging, auto-regulatory or un-druggable targets in various cancers.
- **Multigenic diseases including immunology.** Regulation of multiple genes within an IGD or across IGDs.
- **Regenerative medicine.** Recapitulation of developmental and mature-state gene expression to drive cellular regeneration and restore normal function.
- **Select monogenic diseases.** Correction of dysregulation in monogenic rare and non-rare diseases.

### Our Pipeline

Our pipeline consists of the following programs:

	Target Gene(s)/ EpiZip(s)	Disease(s)	OEC	Discovery	Preclinical	Clinical			
						Phase 1	Phase 2	Phase 3	
Oncology	<b>MYC</b> H3B.08.qX.Y.Z.930	Hepatocellular Carcinoma	OTX-2002	[Progress bar]					
	<b>MYC</b> H2009.08.qX.Y.Z.930	Non-Small Cell Lung Cancer		[Progress bar]					
	<b>Undisclosed</b>	Small Cell Lung Cancer		[Progress bar]					
Multigenic Diseases incl. Immunology	<b>CXCL 1-8</b> A549.04.qX.Y.Z.533	ARDS / COVID-19		[Progress bar]					
	<b>Undisclosed</b>	Idiopathic Pulmonary Fibrosis		[Progress bar]					
Regenerative Medicine	<b>HNF4A</b> HEP.20.qX.Y.Z.552	Liver Regeneration		[Progress bar]					
	<b>Undisclosed</b>	Corneal Regeneration		[Progress bar]					
Select Monogenic Diseases	<b>SFRP1</b> HFDP.08.pX.Y.Z.644	Alopecia		[Progress bar]					

Route of Administration (top to bottom): IV (HCC), IV (NSCLC), IV (SCLC), IV/Pulmonary (ARDS / COVID-19), IV/Pulmonary (IPF), IV (Liver Regeneration), Topical (Corneal Regeneration), Topical (Alopecia)



### Oncology

We are developing OTX-2002 to down-regulate c-Myc, an oncogene that is dysregulated in more than 50% of human cancers and is frequently associated with poor prognosis, as a potential treatment for patients with advanced HCC. In preclinical studies in mice containing human HCC xenografts, we observed tumor growth inhibition of 54% at a dose of 3 mg/kg and of 63% at a dose of 6 mg/kg of our OEC compared to control. We

commenced IND-enabling studies for OTX-2002 for the treatment of HCC in 2021 and expect to submit an IND in the first half of 2022.

We are also developing OECs for the treatment of NSCLC. In preclinical studies in NSCLC xenografts in a mouse subcutaneous tumor model, we observed a 63% inhibition in tumor growth following administration of our OEC compared to control.

We are also developing OEC candidates for the treatment of small cell lung cancer, or SCLC. We have conducted proprietary algorithmic analysis of an IGD that contains a gene that is overexpressed in more than 90% of SCLC. We are generating computationally designed OEC candidates using our OMEGA platform for the potential treatment of SCLC and conducting *in vitro* testing to determine the final OEC candidate for *in vivo* testing.

### **Multigenic Diseases Including Immunology**

We are developing OEC candidates to down-regulate expression of the CXCL1, 2, 3, and IL-8 gene cluster, whose overexpression promotes inflammation, in order to improve disease outcomes in patients with ARDS secondary to COVID-19/SAR-CoV-1 infection or other etiology. In preclinical studies of ARDS, we have observed decreases in gene expression of the CXCL1, 2, 3, and IL-8 gene cluster in cell lines and a 56% reduction in the severity of inflammatory response in mice treated with our OECs.

We are also developing OEC candidates to control expression of genes implicated in patients with idiopathic pulmonary fibrosis, or IPF, to halt or reverse disease progression and improve disease outcomes. We have identified an IGD consisting of genes related to IPF controlled through various intra-IGD interactions and regulatory elements. We are generating computationally designed OEC candidates using our OMEGA platform for the potential treatment of IPF and conducting *in vitro* testing to determine the final OEC candidate for *in vivo* testing.

### **Regenerative Medicine**

We are developing OEC candidates to up-regulate the expression of HNF4 $\alpha$ , a transcriptional master regulator, as a potential way to restore liver-cell function in patients suffering from chronic liver disease, or CLD, including end-stage liver disease, or ESLD. In preclinical studies, we have observed durable increases in HNF4 $\alpha$  and significant improvements in liver histology *in vivo*.

We are also developing OEC candidates to control the expression of genes that have been strongly linked to cell-growth inhibition in patients with diabetes and other conditions to restore the capacity for corneal regeneration. We have identified an IGD containing a master regulatory gene that has been strongly linked to cell-growth inhibition in patients with diabetes and other conditions. We are generating computationally designed OEC candidates using our OMEGA platform for the potential treatment of corneal regeneration and conducting *in vitro* testing to determine the final OEC candidate for *in vivo* testing.

### **Select Monogenic Diseases**

We are developing OECs to down-regulate the expression of SFRP1, a protein that inhibits hair growth, in alopecia, a disease characterized by hair loss on the scalp and body. In preclinical studies in human papilla cells, we have observed a 79% to 88% reduction in SFRP1 mRNA expression in cells treated with our OECs.

## **Intellectual Property and Manufacturing Capabilities**

We have consolidated a significant intellectual property estate covering the OMEGA platform and our OECs through our own development activities and through licenses from the Whitehead Institute at the Massachusetts Institute of Technology, or the Whitehead Institute. We are also developing internal and external manufacturing capabilities, including plans to build our own facility, to provide appropriate scale and quality to support development and commercialization of our OECs.



## Our Strategy

Our objective is to become the leading digital and data-driven epigenetic medicines company by discovering, engineering, developing, manufacturing, and commercializing OECs, utilizing the OMEGA platform, with the vision of selectively directing the human genome to treat and cure serious diseases.

Our strategy includes:

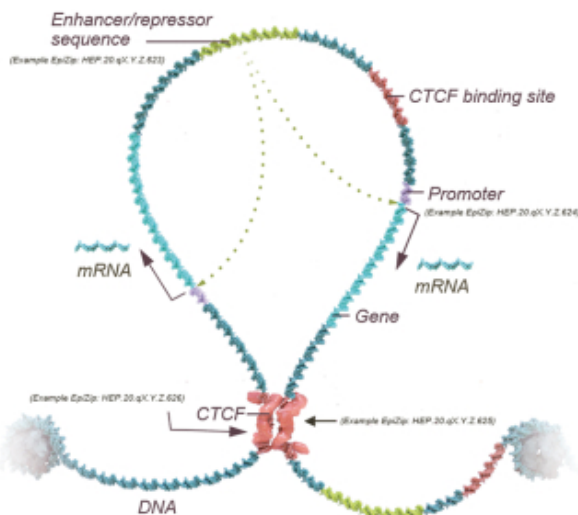
- **Strategically invest in and advance the OMEGA platform.** Our scientific and technical expertise and expansive intellectual property estate have enabled us to develop our industry-leading, pioneering OMEGA platform. We plan to continue to invest in expanding our knowledge of IGD biology and epigenetics in order to identify new DNA-sequence-based epigenomic targets, the EpiZips, further our capacity to innovate and engineer OECs, expand our technologies, broaden our delivery capabilities, and enhance our institutionalized knowledge to further solidify our position as a leading digital and data-driven epigenetic medicines company. We plan to build additional computational, big-data, and advanced-analytic capabilities to maintain our leadership position. We will expand and strengthen our position as leaders in developing mRNA therapeutics for epigenomic control.
- **Establish OECs as a new class of programmable epigenetic mRNA medicine.** Through the breadth of our research-and-development activities and the pursuit of high-value biological targets, we seek to demonstrate the unprecedented therapeutic potential of our OECs and to expand our repertoire of OECs that can be used for therapeutic applications. We have conducted *in vivo* preclinical studies of our OECs in multiple disease models for various indications, including HCC, NSCLC, and ARDS, and we expect to conduct *in vivo* preclinical studies for multiple additional programs. We have initiated IND-enabling studies for our HCC program, and we are aiming to submit an IND for our OEC candidate for the treatment of HCC and declare two OEC development candidates in the first half of 2022. We are also planning to submit an IND for another OEC candidate in the second half of 2022 or early 2023.
- **Expand our pipeline through internal and partnering efforts.** We believe the OMEGA platform can be used to create therapeutics to treat a broad array of human diseases by regulating the expression of single or multiple genes. Internally, we intend to focus our development and commercialization efforts in areas of high unmet need with well-defined and circumscribed patient populations. At the same time, we plan to seek collaborations or co-development programs to mitigate development risk or gain access to novel delivery technologies.
- **Build a fully integrated digitalized biopharmaceutical company.** Our intent is to develop a world-class biopharmaceutical company by leveraging our innate and differentiated platform attributes and digitalized end-to-end capabilities across research, discovery, preclinical and clinical development, manufacturing, and commercial operations. We believe the integrated and modular nature of the OMEGA platform enables iterative learnings and insights for efficient, evidence-based decision making to optimize the engineering, development, and selection of our OEC candidates.
- **Curate world-class talent and culture.** Our culture is guided by our overarching ethos: Ambitious, yet humble. Our unparalleled motivation to transform human medicine through our pioneering work is combined with our underlying sense of humility, which is essential for keeping patients front and center. Given the pioneering nature of our business, identifying, nurturing, developing, and retaining leading talent is a critical element of our strategy.

### Background of Insulated Genomic Domains (IGDs)

Epigenetics is the mechanism that systematically controls every aspect of an organism's life from cell growth and differentiation to cell death. Our team has developed an understanding of the universal operating system of epigenetics and has built the OMEGA platform to replicate nature's method of gene control for therapeutic benefit. IGDs are key to understanding the organization of this operating system and act as the fundamental structural and functional units of gene control and cell differentiation. There are 15,000 IGDs that encompass the roughly 20,000 genes that are distributed across our 23 chromosomes. They are ubiquitous in every cell and evolutionarily conserved within and largely across species.

Gene expression in cells is generally controlled by a highly diverse class of regulatory elements, such as enhancers, repressors and promoters. These regulatory elements are relatively short segments of DNA that act as binding sites for protein transcription factors that in turn recruit other proteins to activate transcription of targeted genes. Current research indicates that genes and their associated regulatory elements reside in a modular fashion within IGDs. The chromosomal-looping structure of IGDs ensures that interactions between genes and their regulatory elements are insulated from neighboring IGDs and extraneous regulatory factors, which is critical for ensuring normal cell-specific gene regulation. The CCCTC-binding factor, CTCF, and the cohesin complex are critical players in the formation and maintenance of the IGD structure. Cohesin is the motor that extrudes and enlarges the IGD loop, while CTCF blocks cohesin from further extrusion and acts as an anchor, thereby enforcing boundaries between IGDs.

### Graphical Representation of an IGD

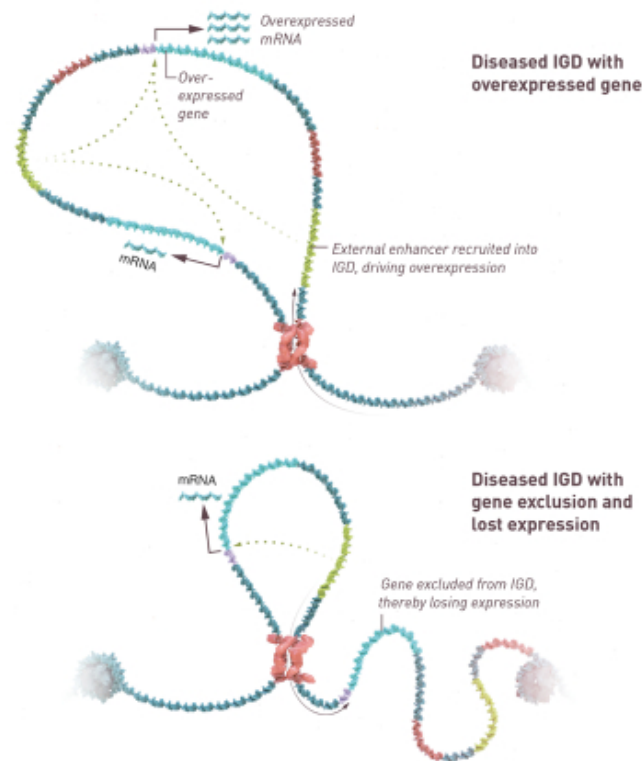


IGDs encompass protein-coding genes and their regulatory elements. A single IGD typically contains between one and ten genes, with a median of three genes. Epigenomic controllers are designed to affect the expression of genes within specific IGDs through precise modulation of one or more IGD components (EpiZips) to control gene expression. Controllers can also be multiplexed to target multiple IGDs.

Any perturbation of an IGD or its boundary has the potential to cause the dysregulation of one or all genes inside it, giving rise to a range of disease states. Alterations of IGDs, which can be either structural or functional in nature, include mutations or disruptions in anchor-CTCF binding sequences, gene promoters, and enhancer regions (including super-enhancers). For example, mutations in the coding sequences for CTCF and cohesin have been observed in various solid-tumor cancers, including breast, prostate, and kidney cancer, as well as in leukemia. IGD boundary alterations may consist of the aberrant inclusion or exclusion of regulatory elements or genes. For example, in some cancers, disruption of the IGD boundary can rewire loop interactions to include strong activating regulatory elements called super-enhancers to upregulate an oncogene. Similar activation can be found in cases of genetic inversion and translocation. Epigenomic changes at the IGD boundary, for example aberrant DNA methylation, can alter CTCF binding and lead to gene exclusion or expose genes within the IGD to

external regulatory elements. Pathological evidence of this disruption has been identified in cancers, such as gliomas, and in inherited human diseases, such as Fragile X syndrome.

### Illustrative Examples of Structurally Dysregulated IGDs



IGD dysregulations can occur also due to functional alterations like those caused by extraneous factors like pathogenic insults, oxidative stress, environmental triggers, etc. These functional changes cause aberrant gene expression.

### OMEGA Epigenomic Programming Platform

We believe that the OMEGA platform represents an unprecedented approach to developing therapeutics to treat the epi genetic basis of disease by precisely controlling gene expression without altering native DNA sequences. We believe that our mRNA-encoded OECs' ability to precisely target and provide tunable and durable effects has the potential to treat a wide range of diseases.

The OMEGA platform consists of four pillars.

#### 1. Proprietary Database of IGDs and EpiZips

We approach target identification starting with validated gene targets linked to a disease indication of interest. We use proprietary algorithms and machine-learning tools to mine our own and public databases to develop a comprehensive profile of the target IGD to understand how it is dysregulated in diseased states. We synthesize this information to determine the key therapeutic intervention points, the EpiZips, to be targeted with OECs to achieve the desired effect on gene expression. Through this process, we have built an expansive library of thousands of EpiZips and IGDs as potential therapeutic targets.



formulations and leverage technological improvements and established regulatory precedents to develop our own LNPs. We are delivering our OECs as mRNA, which encodes the DNA binding domain and epigenetic effector proteins, encapsulated within a LNP. Our LNPs are typically 3- or 4-component molecules that encapsulate nucleic acids like mRNA, protect and transport them to organs and tissues within the body, and facilitate their uptake into cells. We believe our LNPs are capable of providing re-dosable, non-viral, *in vivo* delivery to the liver, lung, central nervous system, immune cells, joints, and other cells and tissues. Once taken up into cells, the LNP enables release of the mRNA cargo into the cytoplasm where it is translated into the OEC, which, in turn, is transported to the nucleus and binds to the targeted EpiZip within the specified IGD. We are currently exploring a range of cationic and ionizable LNPs from various internal and external sources and have developed proprietary LNP formulations that have shown specific and efficient *in vivo* functional delivery in preclinical studies.

#### **4. Industry-Leading Expertise**

We leverage codified learnings and insights gleaned from our lead programs to continue optimizing our platform and inform the discovery and development of subsequent product candidates. We have also established and continue to add to our knowledge bank of EpiZips and OECs. We take a rational and streamlined approach to the development of programmable epigenetic medicines to potentially provide a faster path to the clinic through robust and efficient target identification, validation, product-candidate design, and optimization. We are also continually expanding our catalog of EpiZips and novel and proprietary DNA-binding domains and epigenomic effector proteins and using computational methods to assess on-target and potential off-target binding and activity to minimize inadvertent changes in the expression of genes.

#### **Computational Foundation**

The OMEGA platform leverages novel biology and epigenetics to therapeutically control gene expression and program cell state through our significant computational capabilities. Decoding the rules of the human genome – one with billions of nucleotides, tens of thousands of genes, and up to a million regulatory sequences, all potentially interacting in 3-dimensional space – requires the creation of advanced proprietary algorithms and statistical data analysis techniques. Our cutting-edge computational tools are built on a diverse library of proprietary algorithms and deep-learning techniques, which enable us to interpret and predict the location, structure and function of IGDs. The critical scientific insights provided by the OMEGA platform enable the identification of EpiZips across therapeutic areas and indications. This deep *in silico* understanding and predictability also directly informs the design and rapid engineering of OECs that allow us to regulate single or multiple genes with exquisite specificity, controllable tuning, and duration of effect.

We apply our computational technology throughout the drug development continuum by broadly applying a computation- and data-first approach. We deploy a wide range of systems biology and functional genomics methods to identify relevant biomarkers. We utilize key translational models to validate mechanism of action in order to accelerate development and potentially de-risk clinical translation. Combinatorial optimization techniques and novel discovery efforts enable acceleration of delivery and formulation design. This allows us to rapidly scale programs and manufacturing while improving quality and cost. Systematic data capture and automation have enabled real-time, data-driven decision-making which has further driven our ability to accelerate numerous programs in parallel.

We have a highly skilled computational team with deep expertise and broad experience, supporting the OMEGA platform. This team develops the tools, capabilities, and specialized methods needed to address the complexity of IGD biology, design, and delivery of our OECs, and integration of a computation- and data-first philosophy company wide. We are continually growing and evolving our computational team and capabilities to drive innovation in the discovery and development of programmable epigenetic medicines, manufacturing, and our digital foundation.

#### **Advantages of the OMEGA Platform**

Epigenomic programming is a transformative new approach to biologically engineer programmable epigenetic medicines to treat disease. We believe that our mRNA-encoded OECs' ability to precisely target and

provide tunable and durable effects has the potential to treat a wide range of diseases and has the following advantages:

- **Pioneering IGDs and EpiZips as novel therapeutic targets.** By targeting IGDs and EpiZips, we are controlling the “control room” of biology. This approach allows us to exquisitely control gene expression of single and/or multiple genes, including potentially historically un-druggable genes, in order to treat a wide range of diseases.
- **Precision genomic control with tunable and durable effect with the potential to re-dose.** OECs are designed to up- or down-regulate gene expression to the biologically relevant level to resolve disease. By replicating natural epigenetic marks, our OECs are designed to impart a durable effect without the need for the drug to stay resident in the cells or body. Our OECs are expressed intracellularly and for a controlled duration, which could potentially address safety concerns associated with long-term or permanent residence of drug or components in the body. In addition, because we are using LNPs for delivery, we believe our therapeutic candidates will be re-dosable and may not be associated with the immunogenic risks that are typically seen in viral deliveries such as adeno-associated viruses.
- **Single and/or multiple gene control with a single therapeutic.** Multiple genes in an IGD tend to act along the same disease pathway. Targeting IGDs allows us to use a single therapeutic intervention to control one or many of those genes simultaneously in complex diseases.
- **Ability to multiplex within or across IGDs for synergistic effect.** We can target different EpiZips simultaneously to deliver a synergistic effect within one IGD or among IGDs with multiple OECs.
- **No changes in nucleic acid sequences.** Unlike editing or transgenic approaches, the OMEGA platform enables control of gene expression without changing the inherent nucleic acid sequences and associated risks. Since there is no transfer of DNA, the risk of foreign material integrating into the genome is low, which we believe should lead to lower risk of oncogenesis or other unintended collateral genetic modifications.
- **Ability to accelerate numerous programs in parallel with real-time, data-driven decision-making.** Based on our knowledge base of EpiZips and OECs through application of our computational capabilities, we are able to take a rational and modular approach to discovery and development, allowing us to potentially reduce the time needed to identify, validate, and develop product candidates. We believe our comprehensive understanding of the genomic landscape, proprietary algorithms, extensive data sets, and experience with prior and on-going development efforts enables us to more quickly and efficiently engineer and test potential OECs.

While we are working toward realizing these advantages, our OMEGA platform and our OECs are based on novel technology. Epigenomic controllers present a new class of medicines and have not been evaluated in clinical trials or received regulatory approval. As a result, we may need to develop new evaluation methods or metrics for clinical data, which may make it more difficult to analyze data, or it may take more time or be more costly for us to develop our OECs than other therapeutics for the same indications.

## Our Development Programs

We are currently advancing our development programs in oncology, multigenic diseases including immunology, regenerative medicine, and select monogenic diseases. We have conducted *in vivo* preclinical studies of our OECs in multiple disease models for various indications, including HCC, NSCLC, and ARDS, and we expect to conduct *in vivo* preclinical studies for multiple additional programs. We initiated IND-enabling studies for multiple programs in 2021, and we are aiming to submit an IND for our OEC candidate for the treatment of HCC and declare two OEC development candidates in the first half of 2022. We are also planning to submit an IND for another OEC candidate in the second half of 2022 or early 2023.

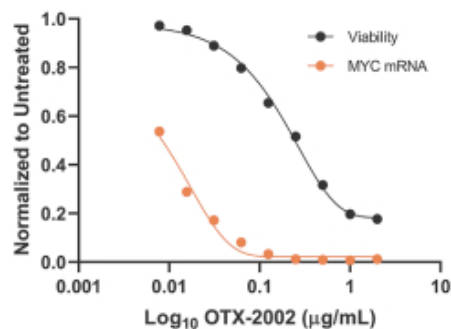
### Oncology

We are developing OTX-2002 for the treatment of HCC. The c-Myc family oncogene is dysregulated in more than 50% of human cancers and is frequently associated with poor prognosis. c-Myc has been shown to play a key role in liver-cell proliferation and is known to be up-regulated in the majority of HCC cases. Drug development aimed at directly targeting c-Myc has proved challenging because its expression is tightly regulated and because it is a protein that lacks a specific active site for small molecule binding. This means that targeting c-Myc mRNA or protein is unlikely to be effective as neither approach addresses the underlying dysregulation at the transcriptional level. Unlike other more binary approaches to downregulation of gene expression, OECs can precisely modulate c-Myc expression enough to kill highly MYC-amplified cancer cells and drive tumor regression, but spare healthy surrounding cells which need only a low level of MYC for normal function. We are developing OTX-2002 for the down-regulation c-Myc in HCC.

HCC is a primary liver malignant tumor that develops in a chronic-liver-disease setting. It is typically diagnosed late in its course and the median survival period following diagnosis is approximately six to 20 months. In 2017, there were an estimated 89,950 people living with liver and liver-related cancer in the United States. Depending on the stage of disease at diagnosis, current treatment options include therapies such as surgical resection, tyrosine kinase inhibitors (TKIs), such as sorafenib, orthotopic liver transplantation or radiofrequency ablation, and for more advanced patients, immune checkpoint plus anti-vascular-endothelial-growth-factor combination therapy, or palliative treatments, such as trans-catheter arterial chemo- or radio-embolization, stereotactic radiation therapy or systemic chemotherapy.

In a preclinical study of OTX-2002 in various HCC cell lines, OTX-2002 down-regulated c-Myc and we observed loss of cellular viability across targeted HCC subtypes with effects observed for 15 days. As shown in the graph below, the EC<sub>50</sub>, which measures the concentration of a drug that provides a 50% response between baseline and the maximum response, was measured in five HCC cell lines. Treatment with OTX-2002 resulted in a c-Myc mRNA expression EC<sub>50</sub> at a mean value 0.013 ug/mL and a 50% decrease in cell viability at 0.147 ug/mL.

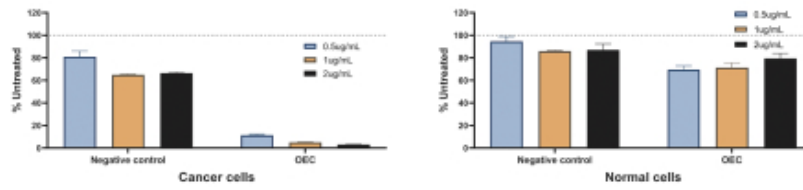
**OTX-2002 was associated with a dose-response on expression and viability (*in vitro*)**



In a separate preclinical study of OTX-2002 in an HCC cell line (Hep3B), we demonstrated a selective effect on the viability of cancer cells. As shown in the graph below, treatment of cancer cells with OTX-2002 at concentrations ranging from 0.5 to 2 ug/mL resulted in a significant reduction in the viability of these cells at all

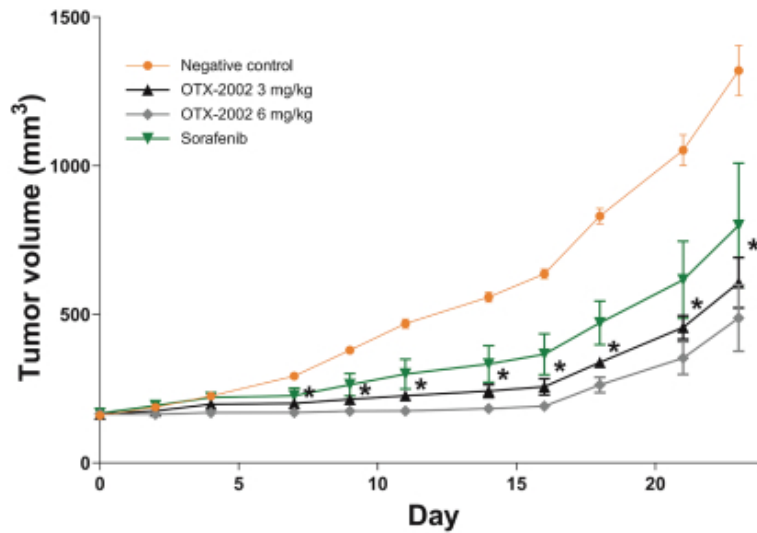
doses, where, by contrast, when we treated normal cells (healthy primary human liver hepatocytes) with OTX-2002 we saw no significant impact on cell viability.

**OTX-2002 reduced viability of HCC cancer cells but not healthy human liver cells (*in vitro*)**  
**Cell Viability**



OTX-2002 delivered via formulated LNPs *in vivo* decreased tumor burden in mice containing human HCC xenografts. In this preclinical study, we administered OTX-2002 in a mouse subcutaneous tumor model at doses of 3 and 6 mg/kg every five days and sorafenib at 50 mg/kg daily. As shown in the graph below, treatment with OTX-2002 at 3 mg/kg was associated with a statistically significant reduction in tumor size following two administrations, resulting in a 54% inhibition of tumor growth by Day 23 compared to negative control. Similarly, treatment with a 6 mg/kg dose of OTX-2002 was associated with a statistically significant reduction in tumor size following two administrations, resulting in 63% lower tumor volume at Day 23 compared to negative control. Treatment with OTX-2002 at 3 mg/kg was equivalent to treatment with sorafenib. Mice treated with OTX-2002 did not experience a significant decrease in body weight. Mice treated with sorafenib experienced an initial drop in body weight with a later gain in overall body weight potentially due to an increase in tumor mass. OTX-2002 was well-tolerated in this study with no adverse events observed.

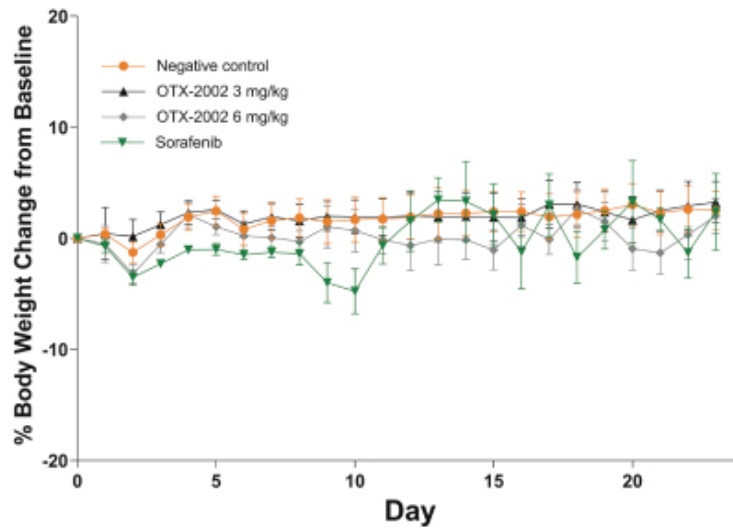
**OTX-2002 anti-tumor activity and dose-dependent response observed in HCC subcutaneous xenograft model (*in vivo*)**



\*  $p < 0.05$  compared to negative control

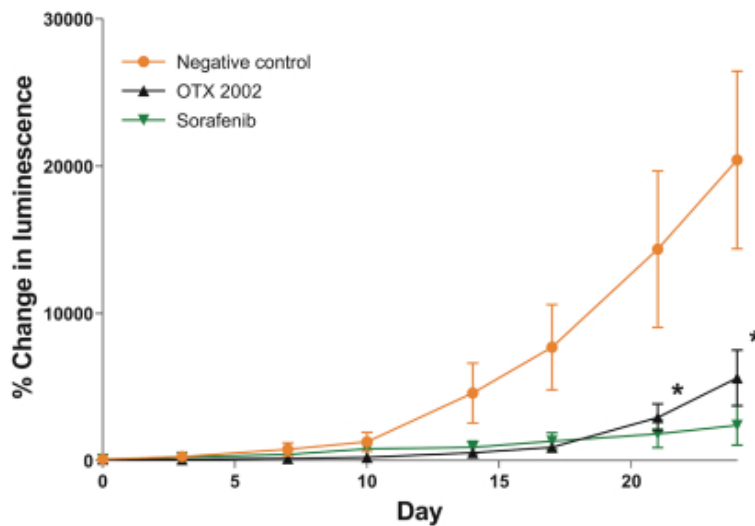


### Change in body weight observed in HCC subcutaneous xenograft model (*in vivo*)



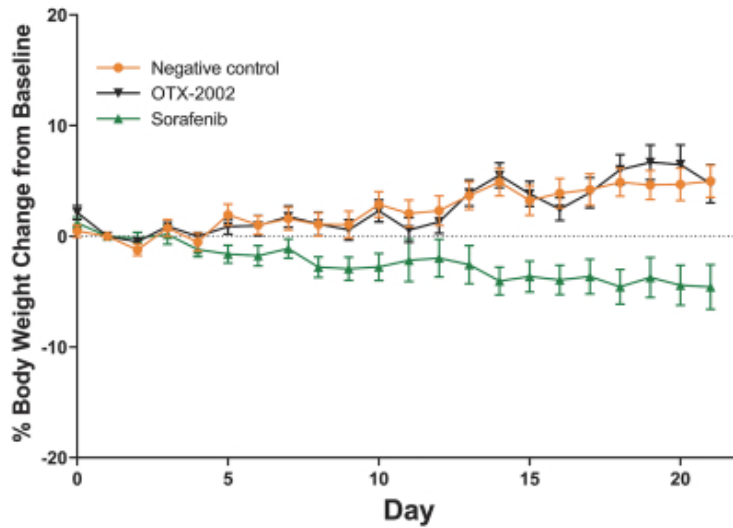
In addition, we observed an equivalent effect on tumor growth from OTX-2002 in mice containing human HCC xenografts compared to sorafenib. Mice were administered 3 mg/kg of OTX-2002 every five days or 50 mg/kg of sorafenib once daily. Tumor growth was measured using bioluminescent imaging. As shown in the graph below, treatment with OTX-2002 resulted in a comparable reduction in luminescence as treatment with sorafenib. Mice treated with OTX-2002 did not experience a significant decrease in body weight. Mice treated with sorafenib experienced a sustained loss in body weight. OTX-2002 was well-tolerated in this study with no adverse events observed.

### OTX-2002 anti-tumor activity observed in HCC orthotopic xenograft model (*in vivo*)



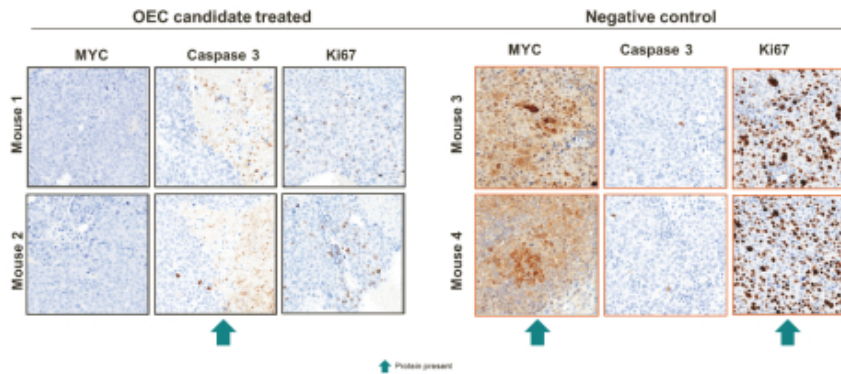
\*  $p < 0.05$  compared to negative control

**Change in body weight observed in HCC orthotopic xenograft model (*in vivo*)**



*In vivo* treatment of OTX-2002 delivered via formulated LNPs in a mouse subcutaneous human HCC tumor model at a doses of 3 mg/kg every five days resulted in decreased tumor burden and also showed correlated changes in c-Myc expression and associated clinical biomarkers in tumors at the cellular level. As shown in the graph below, immunohistochemistry analysis of histology sections from OEC candidate-treated and negative control tumors harvested from the animals in the *in vivo* studies described above showed significant down-regulation of c-Myc protein in the tumors (indicated by loss of brown staining) as well as the expected down-regulation of Ki67 (a biomarker of tumor cell proliferation) and upregulation of Caspase 3 (a biomarker of apoptosis, a type of programmed cell death).

**Change in body weight observed in HCC orthotopic xenograft model (*in vivo*)**



We are conducting additional preclinical studies in subcutaneous and orthotopic liver tumor models and have initiated *in vivo* safety studies. We commenced IND-enabling studies for OTX-2002 for the treatment of HCC in 2021 and expect to submit an IND in the first half of 2022.

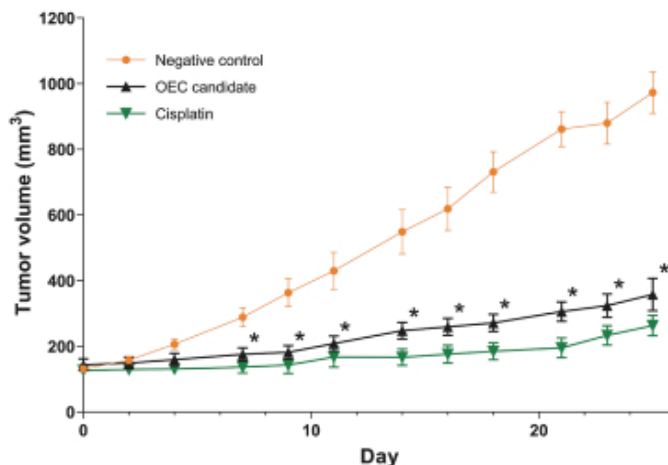
**Non-Small Cell Lung Cancer**

We are evaluating additional epigenetic control points for c-Myc down-regulation in NSCLC. Approximately 50% of NSCLC tumors overexpress c-Myc. We are developing an OEC candidate to down-regulate c-Myc and reduce this overexpression. NSCLC is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses, which was approximately 192,200 new cases in the United States in 2020. The five-year

survival rate for NSCLC is 24%. Depending on the stage of disease at diagnosis, current treatment options include therapies such as surgical resection, photodynamic therapy (PDT), laser therapy, or brachytherapy, chemotherapy, radiation therapy, targeted therapies (e.g., TKIs) and immunotherapy in combination with other therapies.

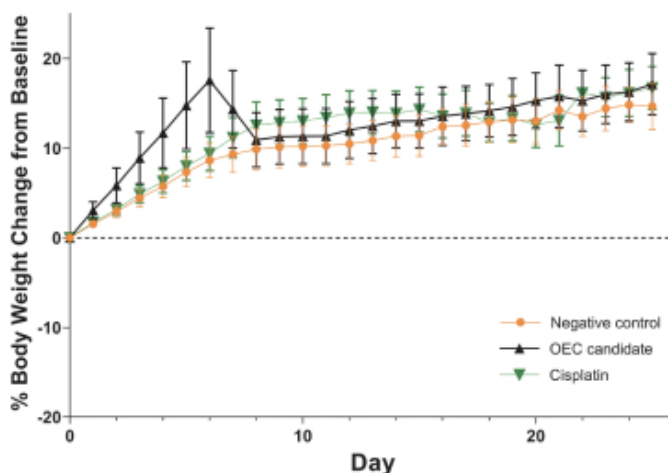
We have identified OEC candidates that have shown activity against a range of NSCLC cell lines *in vitro* in preclinical studies, showing down-regulation of c-Myc with concomitant loss of cellular viability. We also conducted a preclinical study in NSCLC xenografts in a mouse subcutaneous tumor model. In this study, we treated mice with 3 mg/kg of our OEC candidate every five days. Treatment with our OEC candidate showed a statistically significant reduction in tumor size following three administrations, resulting in a 63% lower tumor volume at Day 25 compared to control, with no significant effect on the body weight of treated mice. In this study, treatment with our OEC candidate was associated with an equivalent effect on tumor volume to treatment with cisplatin, a chemotherapy medication used to treat a number of cancers, as shown in the graph below.

#### OEC candidate anti-tumor activity in NSCLC subcutaneous xenograft model (*in vivo*)



\*  $p < 0.05$  compared to negative control

#### Change in body weight observed in NSCLC subcutaneous xenograft model (*in vivo*)



## Small Cell Lung Cancer

We are also targeting SCLC through epigenetic control points that down-regulate a gene known to be overexpressed in more than 90% of SCLC due to a common mutation, and also overexpressed in other cancers including breast, lung, acute myeloid leukemia, and gastric cancers. This gene is located in an identified and well-characterized single-gene IGD. SCLC accounts for 15% of all lung cancers and has a five-year survival rate of 6%. Depending on the stage of disease at diagnosis, current treatment options include surgical resection followed by chemotherapy, chemotherapy with radiation, and immunotherapy.

We conducted proprietary algorithmic analysis of the IGD, using a wide range of multi-omic datasets, to identify numerous EpiZip targets and epigenomic effector options. We are generating computationally designed OEC candidates using our OMEGA platform for the potential treatment of SCLC and conducting *in vitro* testing to determine the final OEC candidate for *in vivo* testing.

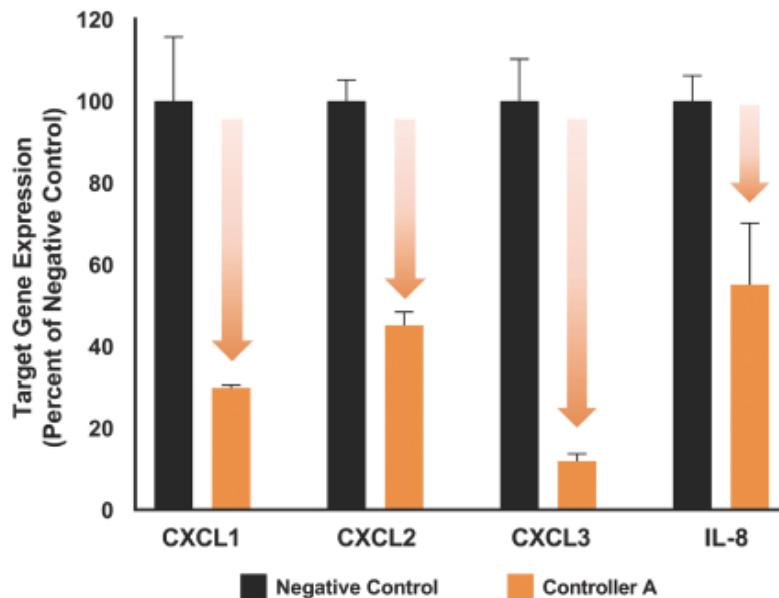
## Multigenic Diseases Including Immunology

### Acute Respiratory Distress Syndrome

We are developing OEC candidates to reduce expression of the CXCL1, 2, and 3 and IL-8 gene cluster in ARDS, including ARDS in COVID-19 patients. Over-expression of the CXCL gene cluster produces chemokines that attract neutrophils and promotes local inflammation. Chemokines that recruit inflammatory cells to the lung are of pivotal importance in the pathogenesis of ARDS and expression of the CXCL1, 2, 3, and IL-8 gene cluster is elevated in the lung cells of patients with ARDS. ARDS is a devastating syndrome, with an incidence of approximately 200,000 in the United States and a mortality rate approaching 40%.

In a preclinical study of an OEC candidate (Controller A in the graph below) in human monocytes, at 24 hours post-dosing we observed a 65% decrease in gene expression of CXCL1, a 55% decrease in gene expression of CXCL2, an 88% decrease in gene expression of CXCL3, and a 52% decrease in gene expression in IL-8, in each case relative to control.

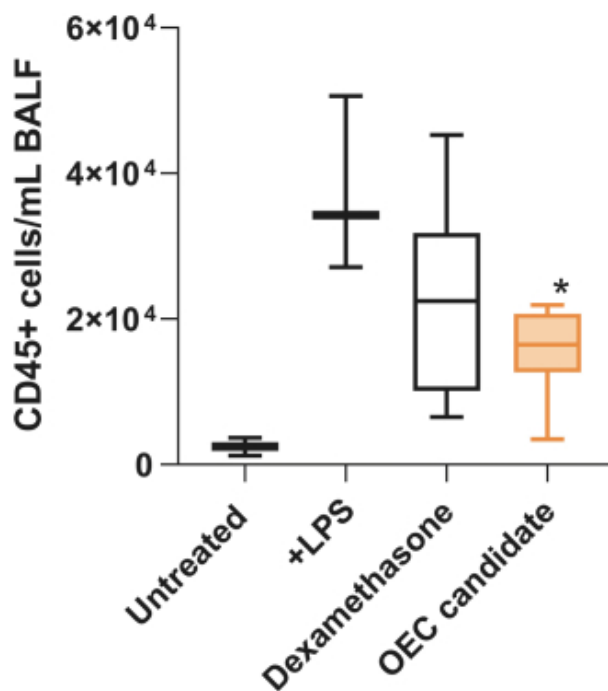
Multigenic IGD targeting of chemokine genes observed (*in vitro*)



In a preclinical study in an animal model of ARDS, we observed a significant decrease in neutrophil infiltration in lungs treated with an OEC candidate. Animals were administered 3 mg/kg of the OEC candidate

(labeled Controller in the graph below) two hours prior and eight hours after lipopolysaccharide insult to induce inflammation or 10 mg/kg dexamethasone daily as a positive control. As shown in the graph below, we observed a 56% decrease in neutrophils infiltration in broncho-alveolar lavage fluid (labeled BALF in the graph below) in mice 72 hours after treatment with the OEC candidate relative to disease control, a measure of the severity of the inflammatory response.

Decreased neutrophil infiltration in ARDS model (*in vivo*)



\*  $p < 0.05$  compared to +LPS

We also plan to conduct *in vivo* testing in other models of severe inflammatory disease where the CXCL1, 2 and 3 and IL-8 gene cluster plays a key role, such as neutrophilic asthma, neutrophilic dermatosis, paw edema, and rheumatoid arthritis.

#### Idiopathic Pulmonary Fibrosis

We are developing OEC candidates to down-regulate expression of a gene cluster known to be up-regulated in patients with IPF and promote pulmonary fibrosis in animal models. IPF is a rapidly progressive and fatal disease in which the lung loses its functional capacity over time. The global prevalence for IPF is roughly 13 to 20 per 100,000 persons, and there is no known cure. The average patient survival is approximately six years with treatment and three years without treatment. Current treatment options are limited to symptomatic or palliative care, including anti-fibrotics, anti-inflammatories, corticosteroids, oxygen therapy, and for advanced disease, lung transplant. If we are able to successfully down-regulate expression of this gene cluster in human lung cells, we believe this OEC candidate could also be developed for severe chronic obstructive pulmonary disease and asthma, as the same gene cluster is implicated in these indications as well as in IPF.

We have conducted algorithmic analysis, using a wide range of multi-omic datasets, to identify an IGD with an internal structure consisting of seven genes related to IPF controlled through various intra-IGD interactions and regulatory elements. We are generating computationally designed OEC candidates using our OMEGA platform for the potential treatment of IPF and conducting *in vitro* testing to determine the final OEC candidate for *in vivo* testing.

## Regenerative Medicine

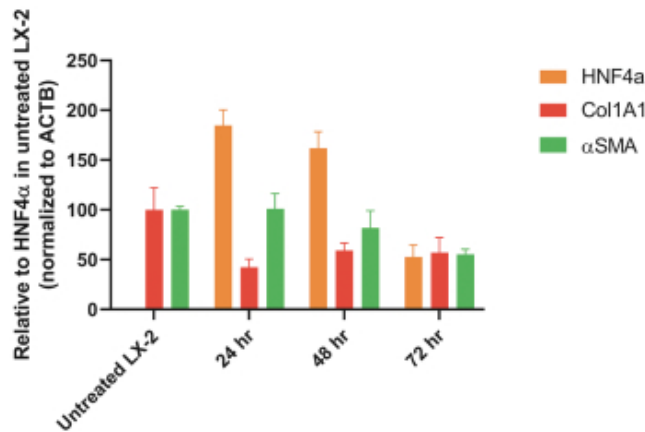
### Liver Regeneration

We are developing OEC candidates designed to increase expression of HNF4 $\alpha$ , a transcriptional master regulator, as a potential way to restore liver-cell function in patients with severe liver dysfunction. HNF4 $\alpha$  controls development, differentiation, and homeostasis of hepatocytes and other cell types in the liver by controlling the expression of proteins, such as bilirubin, albumin, and metabolic enzymes, that are essential for normal liver function. In chronic liver disease, HNF4 $\alpha$  is down-regulated, which contributes to the pathology of liver failure. Studies have shown that increased expression of HNF4 $\alpha$  in even a modest fraction of hepatocytes can restore healthy liver function.

In 2020, chronic liver disease and cirrhosis were a leading cause of death in the United States, accounting for over 50,000 deaths. Depending on the etiology of disease, treatment options may include corticosteroids, antivirals or other drugs, with the final option being liver transplantation. In 2018, in the United States, there were more than 14,000 people on the liver transplant waiting list and approximately 25% died before receiving a transplant.

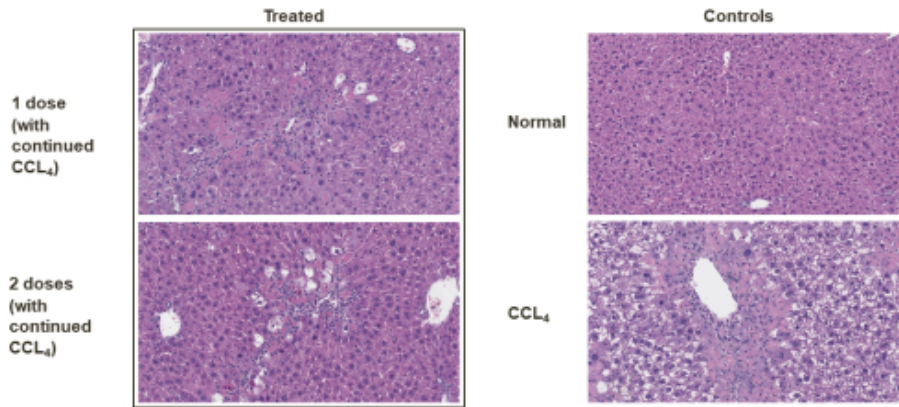
In preclinical studies in primary healthy human hepatocytes, treatment with our OEC candidate induced a durable increase in HNF4 $\alpha$  for up to ten days, which we believe may be sufficient to return hepatocytes to a functional state and restore liver function in CLD and ESLD patients. We also observed decreases in collagen 1A1, or Col1A1, and alpha smooth muscle actin, or  $\alpha$ SMA, both biomarkers of liver injury and fibrosis, as shown in the graph below. At 72 hours, we observed reductions of approximately 50% in both Col1A1 and  $\alpha$ SMA relative to untreated cells. These data showed a reduction in expression of these downstream biomarkers of liver damage in response to the up-regulation of HNF4 $\alpha$  and support the proposed therapeutic mechanism of action of our OEC candidate.

#### OEC candidate reduced biomarkers of liver damage (*in vitro*)



As shown in the images below, in an *in vivo* preclinical mouse liver fibrosis model, carbon tetrachloride treatment was used to induce hepatocellular degeneration (labeled CCL<sub>4</sub> in the images below). Treatment with a mouse surrogate construct of our OEC candidate showed a significant decrease in hepatocellular degeneration on Days 31 and 38 with either one or two weekly administrations.

## Mouse surrogate construct of OEC candidate improved liver histology (*in vivo*)



We are currently conducting additional *in vitro* and *in vivo* pharmacology, formulation optimization, efficacy, and preliminary safety studies of our OEC candidate.

### Corneal Regeneration

We are also developing OEC candidates to control the expression of multiple potential target genes in patients with diabetes and other conditions to treat corneal epithelial injury. The proteins expressed by these genes have been strongly linked to cell-growth inhibition and shown to be key factors in preventing ocular wound-healing in animal models. Approximately 70% of patients with diabetes suffer from corneal complications, including epithelial fragility, recurrent erosions, ulcers, and delayed or incomplete wound repair. Diabetic retinopathy is currently the leading cause of legal blindness in working age adults worldwide. The condition is mainly treated by attempting to maintain tight blood glucose control. We believe that by tuning these genes, we may be able to facilitate corneal regeneration to treat these corneal complications from diabetes or other conditions.

We have identified an IGD containing a master regulatory gene that has been strongly linked to cell-growth inhibition in patients with diabetes and other conditions. We conducted algorithmic analysis of the IGD, using a wide range of multi-omic datasets, to identify numerous EpiZip targets and epigenomic effector options. Using our OMEGA platform, we are generating computationally designed OEC candidates for the potential treatment of corneal generation and conducting *in vitro* testing to determine the final OEC candidate for *in vivo* testing.

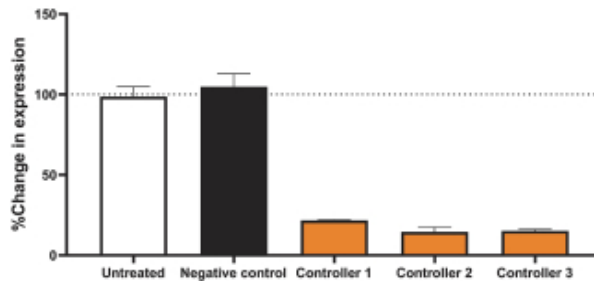
### Select Monogenic Diseases

#### Alopecia

We are developing OEC candidates for the treatment of alopecia, a disorder characterized by patches of non-scarring hair loss affecting the scalp and body. We are targeting SFRP1, a protein that inhibits hair growth in alopecia patients, and are developing OEC candidates designed to down-regulate the production of SFRP1. Alopecia areata affects approximately 6.5 million people in the United States and approximately 2% of people worldwide. Androgenetic alopecia, also known as male pattern baldness, is a genetically predetermined disorder caused by excessive response to androgens, which affects up to 50% of males and females. There is currently no cure for either type of alopecia. We are currently evaluating delivery of our OEC candidates to the hair bulb and assessing our OEC candidates' effects in *ex vivo* models of hair growth.

In a preclinical study, we treated patient human papilla cells with an OEC candidate and measured SFRP1 mRNA expression. As shown in the figure below, we observed a 79% to 88% reduction in SFRP1 mRNA expression in cells treated with the OEC candidate compared to control. These effects were observed through Day 7.

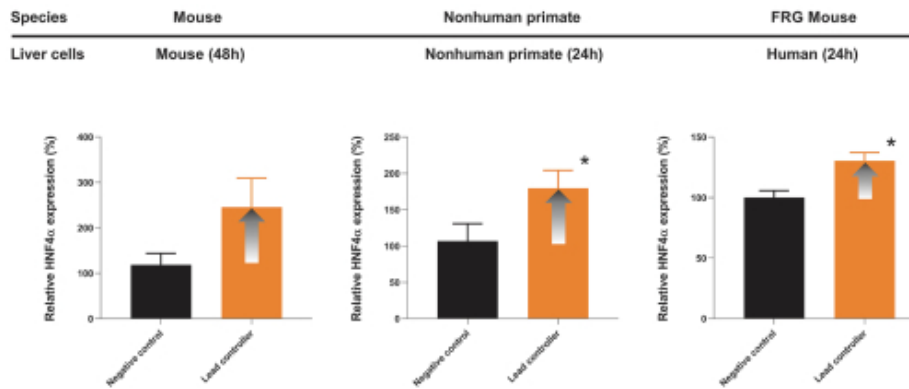
### Decrease in SFRP1 mRNA expression in human papilla cells (*in vitro*)



### Translational Data

A critical element for the clinical translation of our OEC candidates is our ability to design OEC candidates that can target IGDs and tune gene expression across species. In preclinical studies, we evaluated changes in HNF4 $\alpha$  expression in non-human primates and in human liver tissue engrafted and grown in a mouse (labeled FRG Mouse in the graph below) treated with our OEC candidate and in healthy mice treated with an OEC candidate designed to target the homologous murine target sequence. As shown in the graph below, we observed therapeutically relevant up-regulation of HNF4 $\alpha$  compared to control, with results showing a 246% increase in mice, 68% increase in non-human primates, and 31% increase in the FRG mouse. We believe that this translational fidelity of our mechanism of action supports our continued development of our OEC candidates and programs.

### Omega Epigenomic Controllers increased HNF4A expression in preclinical studies (*in vivo*)



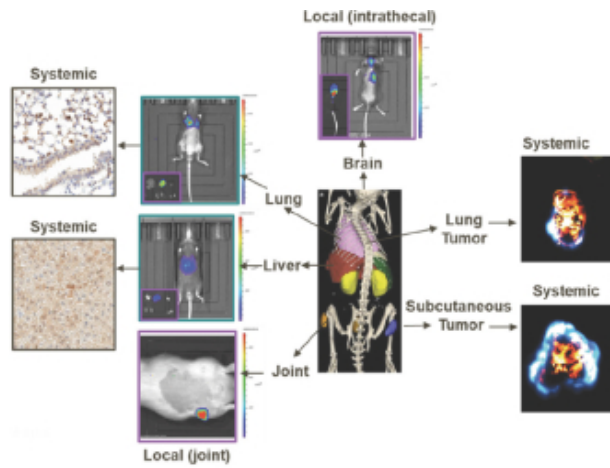
\*  $p < 0.05$  compared to negative control

### Delivery Data

We have extensive internal formulation, delivery and development expertise in mRNA and LNPs, and are engaged in continuous internal LNP research and development. We are currently exploring a range of LNPs from various internal and external sources and have developed proprietary formulations that have shown specific and efficient *in vivo* functional delivery of our OEC candidates to a number of therapeutically relevant cell and tissue-types in preclinical studies, as shown in the figure below. The tissue and cell types we can access with our current library of LNP compositions include liver (e.g. hepatocytes, stellate cells, Kupffer cells), lung (e.g. endothelial, alveolar, epithelial), local joints (e.g. synovial layer, chondrocytes, immune cells), and the central nervous system (e.g. spinal cord, brain), as well as tumors (e.g. subcutaneous, orthotopic). Collectively, our current delivery capabilities enable us to develop and expand our pipeline.



## Delivery Omega Epigenomic Controllers



## Manufacturing

We view the development of manufacturing capability, capacity, and control as critical to our overall success and specifically to our ability to meet our development timelines, contain operational costs and generate and protect intellectual property for our platform technology and product candidates. Because of this, we have chosen a clinically validated manufacturing and delivery technology with which we have deep internal expertise and which is similar to that being developed for various applications in the fields of vaccine development and gene editing. We are thus able to leverage our own experience, as well as the technological improvements and regulatory precedents established by previous and current products utilizing the same modalities.

Our internal process and analytical development organization has established manufacturing processes at sufficient scale to supply our research and early preclinical development requirements for drug substance and drug product. In addition, we have engaged highly skilled third-party contract development and manufacturing organizations, or CDMOs, with extensive experience in manufacturing mRNA, our drug substance, and drug product to implement our manufacturing processes at large scale under current good manufacturing practices, or cGMP. We have established manufacturing services agreement with third-party CDMOs for the supply of drug substance and drug product to meet our needs for preclinical studies, IND-enabling toxicology studies and clinical trials. We expect to continue to rely on third-party CDMOs for the supply of drug substance, drug product and finished product for the next several years. Given the critical reliance of our overall success on manufacturing supply of our products, we are in the process of constructing a cGMP facility to manufacture material for our pre-clinical and clinical needs.

For each of our therapeutic programs, we evaluate the optimal LNP delivery options from both external collaborations and our internal LNP research and development platform. For our lead program, OTX-2002, we have licensed LNP technology from Acuitas Therapeutics, Inc., or Acuitas, a company with extensive LNP intellectual property and a track record of collaborating and developing LNPs for clinical use. We believe our collaboration with Acuitas will provide significant formulation and manufacturing expertise that will facilitate the transfer of processes for LNP formulation of mRNA under cGMP standards to CDMOs. We are also in the process of engaging additional highly experienced CDMOs to manufacture our product candidates.

We believe that we have sufficient manufacturing capacity through our third-party CDMOs and current internal facilities to meet our current research, preclinical, and clinical material needs. We believe that the current manufacturing capacity established externally, together with the internal capacity and our planned manufacturing facility will be sufficient to meet our anticipated needs for the next several years. We monitor the capacity availability for the manufacture of drug substance and drug product and believe that our supply agreements with our CDMOs and the lead times for new material supply would allow us to access additional capacity to meet our anticipated needs. We also believe that our product can be manufactured at a scale and with production and procurement efficiencies that will result in commercially competitive costs.

## Competition

As an early-stage biotechnology company, we face competition from a wide array of companies in the pharmaceutical and biotechnology industries. This competition includes both small companies and large companies with greater financial and technical resources and longer operating histories than our own. We also compete with the intellectual property, technology, and product development efforts of academic, governmental, and private research institutions.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly if they establish collaborative arrangements with large companies.

The key competitive factors affecting the success of any products that we develop, if approved, are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payors. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are 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 may also obtain U.S. Food and Drug Administration, or FDA, or other regulatory approval for their products more rapidly than we may obtain approval for ours, and may commercialize products more quickly than we do.

We are aware of only two other companies that have recently formed to develop epigenomic therapies: Chroma Medicines and Tune Therapeutics. In addition, we expect to compete with companies developing technologies that focus on gene-expression control using various technologies, such as CRISPR gene editing, gene therapies, non-coding RNA therapeutics, and small molecule epigenetics. These companies include: Alnylam Pharmaceuticals, Inc., Beam Therapeutics Inc., Biogen Inc., Constellation Pharmaceuticals, Inc., CRISPR Therapeutics AG, Editas Medicine Inc., Epizyme Inc., Ionis Pharmaceuticals, Inc., Intellia Therapeutics, Inc., Janssen Pharmaceutical Companies of Johnson & Johnson, Pfizer Inc., and Sangamo Therapeutics Inc.

Further, while we are not aware of other companies developing epigenomic controllers and modulating gene-expression pre-transcriptionally for the treatment of either HCC or NSCLC, several companies are developing therapeutics that use gene-expression control for the treatment of HCC or NSCLC, including Ionis Pharmaceuticals, Inc., AstraZeneca plc, Alnylam Pharmaceuticals, Inc. / Ascleptis Pharma Inc. and Bio-Path Holdings, Inc., which are developing anti-sense inhibitors, Nitto Denko Corporation and Simaomics, Inc., which are developing siRNA inhibitors, InteRNA Technologies B.V. which is developing micro-RNA mimic therapies, Momotaro-Gene Inc. and Genprex, Inc., which are developing gene therapy approaches, and MiNA Therapeutics Limited, which is developing a small activating RNA therapy.

These technologies, along with other modalities, such as small molecules and biologics, may be used to develop therapeutic candidates that would compete against our current, and potentially future, product candidates. In addition, we expect any OECs we develop to compete with established therapeutic treatments, if any, in their target indication.

## Intellectual Property

We believe our intellectual property estate is a strategic asset that has the potential to provide us with a competitive advantage. We strive to protect our proprietary technology, inventions and improvements that are commercially important to our business, including pursuing, maintaining, defending, and asserting patent rights, whether developed internally or licensed from third parties. Our policy and practice is to protect our proprietary position by various methods, including filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology (e.g., OMEGA platform, OECs, delivery and manufacturing technology), inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates. We continue to innovate and pursue in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of epigenetic medicine. We additionally rely on data

exclusivity, market exclusivity and patent term extensions when available and plan to seek and rely on regulatory protection afforded through orphan drug designations for our therapeutic products. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

Our wholly owned and in-licensed patent portfolio cover various aspects of the OMEGA platform, including, manufacturing, delivery, OECs and our therapeutic programs. Our patent portfolio also covers our product candidates that are in development. As of December 31, 2021, our patent portfolio consists of 28 patent families, including 40 pending U.S. patent applications (including provisional applications), 90 pending foreign patent applications in Europe, Australia, Canada, China, Hong Kong, Mexico, and Japan, and nine owned or in-licensed Patent Cooperation Treaty (PCT) applications that have not entered national phase. Any US or foreign patents issuing from or claiming priority to the patent applications in our patent portfolio will expire between 2036 and 2042, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees. Our objective is to continue to expand our patent portfolio to protect our proprietary technology (including the OMEGA platform, OECs, delivery and manufacturing technology), inventions, improvements and current and future product candidates. Our patent portfolio currently does not include any granted patent covering any of our product candidates.

Further details of the products and technology areas covered by our intellectual property portfolio are described below.

### **OMEGA Platform-related intellectual property**

Our intellectual property portfolio includes know-how and patent rights directed to the OMEGA platform and delivery technology developed internally and in-licensed exclusively or co-exclusively from the Whitehead Institute for Biomedical Research, or WIBR, and Flagship Pioneering Innovations V., Inc., or Flagship.

The intellectual property portfolio for our OMEGA platform technology is comprised of patent rights directed to compositions and methods of using OECs; methods and compositions for upregulating or downregulating gene expression by targeting IGDs; compositions for modulating gene expression by targeting IGDs with epigenetic effectors, physical disruptors and genetic modifiers; and methods for identifying and interrogating IGDs. The portfolio relates broadly to our existing product candidates and those we may develop in the future and the indications we target or may target in the future. We in-license the patents and patent applications related to our OMEGA platform from WIBR and from Flagship. As of December 31, 2021, we in-licensed one issued U.S. patent, 12 non-provisional U.S. patent applications and five provisional U.S. patent applications; four PCT patent applications; and 24 foreign patent applications in Europe, Australia, Canada, China, Hong Kong, Japan, and Mexico. We expect patents issuing from or claiming priority to these pending applications, if any, to expire between 2036 and 2042, excluding any patent term adjustments or extensions. The foregoing account of our patent rights does not include rights to patents and patent applications owned by Acuitas and in-licensed to Omega pursuant to a non-exclusive license agreement.

The patent portfolio for our delivery technology is comprised of patent applications directed to LNP formulations and cell penetrating polypeptide compositions and their uses. We own certain of the patent applications related to our delivery technology and in-license certain of the patent applications from Flagship. As of December 31, 2021, we owned or in-licensed one provisional U.S. patent applications, one nonprovisional U.S. patent application, and one PCT application. We expect patents issuing from or claiming priority to these pending applications, if any, to expire between 2037 and 2042, excluding any patent term adjustments or extensions.

### **Disease-related intellectual property**

The disease-related patent rights in our intellectual property portfolio provide coverage for OECs that specifically address certain conditions and the associated disease states. The disease-related patent applications for our lead programs include those described below. Each of the disease-related patent applications described below is either wholly owned by us or is exclusively or co-exclusively licensed from WIBR or Flagship.

## **MYC**

Our OTX-2002 program targets the c-Myc family oncogene. We have developed OECs that downregulate c-Myc for the treatment of HCC. We also have a program designed to reduce the expression of c-Myc to treat NSCLC. As of December 31, 2021, we in-licensed from WIBR and Flagship one U.S. non-provisional patent application, two foreign patent applications in Europe and Hong Kong, and one PCT application related to OEC compositions of matter, methods of treating c-Myc related cancers and methods of modulating c-Myc expression. We expect patents issuing from or claiming priority to these pending patent applications, if any, to expire between 2037 and 2041, excluding any patent term adjustments or extensions.

## **CXCL1, 2, 3, and IL-8**

We are developing OEC candidates to reduce expression of the CXCL1, 2, 3, and IL-8 gene cluster. The program is designed to reduce expression of chemokines that are over-expressed in a broad range of inflammatory disorders, including rheumatoid arthritis, gout, neutrophilic asthma, and ARDS. We are currently developing OEC candidates that target a key CTCF binding site of the CXCL 1-3/IL-8 IGD. As of December 31, 2021, we in-licensed from Flagship one PCT application relating to OEC compositions that target the CXCL 1-3/IL-8 IGD, and methods of treating inflammatory disorders, including rheumatoid arthritis. We expect patents claiming priority to this pending patent application, if any, to expire in 2041, excluding any patent term adjustments or extensions.

## **HNF4a**

Our liver regeneration program targets the master transcriptional regulator HNF4a. We have developed OEC candidates that increase expression of HNF4a to restore liver-cell function in patients with severe liver dysfunction. As of December 31, 2021, we owned one U.S. non-provisional patent application and one PCT application related to OEC compositions of matter and methods of treating liver disease. We expect patents issuing from these pending patent applications, if any, to expire in 2040, excluding any patent term adjustments or extensions.

## **Other Disease Areas**

In addition to our disease programs listed above, we also have patent applications relating to novel OEC compositions and their use for treating additional disorders that would benefit from upregulation or downregulation of gene expression. As of December 31, 2021, we owned one PCT patent application directed to compositions and methods of treatments for neurological disorders. We expect patents issuing from or claiming priority to these pending applications, if any, to expire between 2040 and 2042, excluding any patent term adjustments or extensions. As of December 31, 2021, we owned one PCT patent application directed to compositions and methods of treatment for metabolic disorder. We expect patents claiming priority to this pending application, if at all, to expire in 2040, excluding any patent term adjustments or extensions. As of December 31, 2021, we in-licensed from WIBR and Flagship two U.S. non-provisional patent applications and one European patent application directed to compositions and methods of treatment for cancer. We expect any patents issuing from these pending applications, if any, to expire between 2036 and 2039, excluding any patent term adjustments or extensions. As of December 31, 2021, we owned one PCT patent application directed to compositions and methods of treatment for inflammatory disorders. We expect patents claiming priority to this pending application, if at all, to expire in 2041, excluding any patent term adjustments or extensions. As of December 31, 2021, we owned one U.S. provisional patent application directed to compositions and methods of treatments for alopecia. We expect patents issuing from or claiming priority to this pending application, if any, to expire in 2042, excluding any patent term adjustments or extensions.

We intend to continually assess and refine our intellectual property strategy and file additional patent applications as we develop new platform technologies and product candidates.

## **License Agreements**

We are a party to license agreements under which we license patents, patent applications, and other intellectual property from third parties. The licensed intellectual property covers, at least in part, methods and

compositions for regulating gene expression by targeting IGDs. 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.

### ***License Agreement with Flagship***

In March 2019, we entered into an agreement, or the Flagship Agreement, with Flagship, pursuant to which we (i) irrevocably and unconditionally assigned to Flagship all of our right, title and interest in and to certain foundational intellectual property conceived prior to the "Launch of the Company", which is defined as the earlier of our closing of the Series B financing or the first day of employment by our CEO (such foundational intellectual property, the Foundational IP) and (ii) obtained an exclusive, worldwide, royalty-bearing, sublicensable, transferable license from Flagship under such Foundational IP to develop, manufacture and commercialize any product or process or component thereof, the development, manufacturing and commercialization of which would infringe at least one valid claim of Foundational IP absent the license granted under the Flagship Agreement in the field of therapeutics during the term of the Flagship Agreement. In addition, Flagship irrevocably and unconditionally assigned to us all of its right, title and interest in and to any and all patents claiming any inventions conceived (i) solely by Flagship Pioneering, Inc., or Flagship Management, or jointly by Flagship Management and us, (ii) after the "Launch of the Company", and (iii) as a result of activities conducted pursuant to that certain managerial agreement with Flagship Management, or the Managerial Agreement, or other participation of Flagship Management in our affairs, but excluding Foundational IP. Foundational IP is directed, among other things, to the OMEGA platform, including to general methods and compositions (OECs) to modulate gene expression by targeting IGDs and specific compositions and methods directed to specific targets for the treatment of various disorders, such as MYC and CXCL1, 2, 3 & IL-8 related disorders. We utilize the rights granted by Flagship under the Flagship Agreement in our OMEGA platform and our therapeutic product candidates, including our therapeutic programs directed to MYC and CXCL1, 2, 3 & IL-8 programs. As of December 31, 2021, the Foundational IP was expected to expire between 2037 and 2042. The license granted to Foundational IP is contingent upon our compliance with our obligations under the Flagship Agreement. Our obligations under the Flagship Agreement include the use of commercially reasonable efforts to develop and commercialize licensed products and payments required under the Flagship Agreement, including royalties on net sales of the licensed products. Pursuant to the Flagship Agreement, we are obligated to pay Flagship, on a licensed product-by-licensed product and jurisdiction-by-jurisdiction basis, royalties in the low single-digit percentage on net sales of licensed products. We are solely responsible for the clinical development of any product candidates we develop based on the Foundational IP. Under the Flagship Agreement, Flagship retains the right to practice Foundational IP within the field of therapeutics solely for non-commercial research and development purposes and to perform its duties under the Managerial Agreement.

The Flagship Agreement will terminate on the last to expire royalty term, which will expire, on a licensed product-by-licensed product and jurisdiction-by-jurisdiction basis, upon the expiration of the last valid claim of any Foundational IP covering such licensed product. Upon expiration of the royalty term with respect to a licensed product in any jurisdiction and payment in full of all amounts owed under the Flagship Agreement for such licensed product, the license granted to us will automatically convert into a non-exclusive, fully paid up license for such licensed product in such jurisdiction. We have the right to terminate the Flagship Agreement in its entirety for convenience upon 60 days of written notice. Either party may terminate the Flagship Agreement upon a material breach by the other party that is not cured within 30 days after receiving written notice. Also, Flagship may terminate (i) upon 30 days' written notice if we cease to carry on our business with respect to the rights granted in the Flagship Agreement, (ii) upon written notice if we experience an event of bankruptcy, or (iii) immediately upon written notice if we challenge the validity, patentability, or enforceability of any Foundational IP or participate in any such challenge. If Flagship determines that we have not used commercially reasonable efforts to develop and commercialize a licensed product in a specific sub-field within the licensed field, Flagship has the right to terminate the license, on prior written notice, with respect to such licensed product in such sub-field. However, in such event, we may retain our license with respect to such licensed product and sub-field if Flagship approves a written plan for development and commercialization.

### ***Exclusive and Co-Exclusive License Agreements with WIBR***

In May 2019, we and WIBR entered into an exclusive license agreement, or the WIBR Exclusive Agreement. Under the WIBR Exclusive Agreement, we received an exclusive, worldwide, royalty-bearing,

sublicensable license under certain patent rights owned or controlled by WIBR to research, make, have made, use, sell, offer to sell, lease and import products and to perform and have performed licensed processes in the field of human and animal therapeutics and diagnostics. The licensed patents under the WIBR Exclusive Agreement are directed to, among other things, methods and compositions for modulating gene expression in IGDs.

In May 2019, we also entered into a co-exclusive license agreement with WIBR, or the WIBR Co-Exclusive Agreement. Under the WIBR Co-Exclusive Agreement, we received a co-exclusive, worldwide, royalty-bearing, sublicensable license under certain patent rights owned or controlled by WIBR to research, make, have made, use, sell, offer to sell, lease and import products and to perform and have performed licensed processes in the field of human and animal therapeutics and diagnostics. Our co-exclusive rights under the WIBR Co-Exclusive Agreement will become exclusive if the co-exclusive license agreement between WIBR and the co-exclusive licensee is terminated at any time for any reason. The licensed patents under the WIBR Co-Exclusive Agreement are directed to, among other things, methods and compositions for modulating gene expression through targeting IGDs. The WIBR Exclusive Agreement and the WIBR Co-Exclusive Agreement are collectively referred to as the WIBR Agreements.

Under the WIBR Agreements, WIBR retains the right to practice the licensed patents for research, teaching, and other educational purposes, including use in third-party sponsored research, and to grant non-exclusive licenses to other academic and not-for-profit research institutes solely for non-commercial research, teaching, and other educational purposes.

The licenses granted to us under the WIBR Agreements are subject to certain preexisting rights held by the U.S. government. The U.S. government retains certain rights under applicable law with respect to licensed patents that arose from federal research funding. The license granted to us under the WIBR Agreements is further subject to certain preexisting rights held by a certain third party who is a party to a certain sponsored research agreement, or SRA, with WIBR. Under the SRA, WIBR covenanted not to sue said third party if certain inventions arising under the SRA, or SRA inventions, are dominated by the licensed patents and we are thereby excluded from asserting any patent rights licensed from WIBR that cover the SRA inventions against said third party. Furthermore, beginning five years after the effective date of the WIBR Exclusive Agreement, if WIBR or we receive a request from a third party for a sublicense under the licensed patent rights to make, have made, use, sell, offer to sell, or import a product or process that is not directly competitive with a licensed product or licensed process then offered for sale or in bona fide research or development by or on behalf of us, we must either (i) enter into a good faith negotiation toward granting a non-exclusive sublicense limited to the third party's proposed field and proposed product, or (ii) at our election, submit a plan for WIBR's approval for development of the proposed product, which approval must not be unreasonably withheld.

Under the WIBR Exclusive Agreement, we are required to pay WIBR an annual license maintenance fee in the mid five figures. WIBR is also entitled to receive potential clinical and regulatory milestones up to \$1.7 million in the aggregate for each of the first three licensed products (excluding backup products). During the year ended December 31, 2021, we incurred approximately \$0.1 million of expenses, consisting of license maintenance fees, reimbursable patent costs and milestone payment, under the WIBR Exclusive Agreement. With respect to the sale of licensed products by us, our affiliates or our sublicensees, WIBR is entitled to receive a low single-digit percentage royalties on net sales of licensed products until, on a country-by-country basis, the expiration or abandonment of the patent rights. We are entitled to certain customary reductions and offsets on these royalties with respect to a licensed product in a given country. If we sublicense our rights to develop or commercialize a licensed product under the WIBR Exclusive Agreement, WIBR is entitled to a percentage of non-royalty payments that we receive from our sublicensees, ranging from zero to the low double-digits, depending on the stage of development our licensed products at the time such sublicense is executed.

Unless earlier terminated, the WIBR Exclusive Agreement will remain in effect until the expiration or abandonment of all licensed patent rights. We may terminate the WIBR Exclusive Agreement at our convenience following written notice to WIBR. Either party may terminate the WIBR Exclusive Agreement for an uncured material breach of the other party. WIBR may also terminate the WIBR Exclusive Agreement in the event that Omega ceases to carry on its business. The last to expire patent under the WIBR Exclusive Agreement, if issued, is expected to expire in 2038.

Under the WIBR Co-Exclusive Agreement, we are required to pay WIBR an annual license maintenance fee in the low to mid five figures. WIBR is also entitled to receive potential clinical, regulatory, and sublicensing milestones up to \$1.9 million in the aggregate for each of the first three licensed products (excluding backup products). During the year ended December 31, 2021, we incurred less than \$0.1 million of expenses, consisting of license maintenance fees and reimbursable patent costs, under the WIBR Co-Exclusive Agreement. With respect to the sale of licensed products by us, our affiliates or our sublicensees, WIBR is entitled to receive a sub single digit percentage royalties on net sales of licensed products and low single digit percentage royalties on licensed services income until, on a country-by-country basis, the expiration or abandonment of the patent rights. We are entitled to certain customary reductions and offsets on these royalties with respect to a licensed product in a given country. If we sublicense our rights to develop or commercialize a licensed product under the WIBR Co-Exclusive Agreement, WIBR is entitled to a mid-five figure yearly payment for each such sublicense agreement that grants a sublicensee the right under the licensed patents.

Unless earlier terminated, the WIBR Co-Exclusive Agreement will remain in effect until the expiration or abandonment of all licensed patent rights. We may terminate the WIBR Co-Exclusive Agreement at our convenience following written notice to WIBR. Either party may terminate the WIBR Co-Exclusive Agreement for an uncured material breach of the other party. WIBR may also terminate the WIBR Co-Exclusive Agreement in the event that we cease to carry on our business. The last to expire patent under the WIBR Co-Exclusive Agreement, if issued, is expected to expire in 2037.

## **Agreements with Acuitas**

### *Development and Option Agreement*

In October 2020, we and Acuitas entered into a development and option agreement, or the Acuitas Option Agreement. Under the Acuitas Option Agreement, the parties agreed to jointly develop certain products combining our gene modulating therapeutics with Acuitas's LNPs. Each party granted the other party a worldwide, non-exclusive, royalty-free license under its proprietary technology to conduct the joint research. We will pay Acuitas's personnel costs and external expenses incurred in performing research in accordance with a work plan under the Acuitas Option Agreement. Under the Acuitas Option Agreement, Acuitas granted us options to obtain non-exclusive, worldwide, sublicensable licenses under Acuitas's patent rights and know-how related to LNP technology, or Acuitas LNP Technology, with respect to two specified targets (e.g., OEC constructs), or Reserved Targets, to develop and commercialize one or more therapeutic products including mRNAs that encode the Reserved Targets. For each option and Reserved Target, we are obligated to pay an annual technology access fee and target reservation and maintenance fees collectively in the low-mid six figures until such Reserved Targets is removed from the Reserved Target list or until we exercise an option with respect to such Reserved Target. On exercise of the first option, we are required to pay a \$1.5 million option exercise fee after execution of the first non-exclusive license. On exercise of the second option, we are required to pay a \$1.75 million option exercise fee after execution of the second non-exclusive license. During the year ended December 31, 2021, we incurred total expenses of \$1.9 million under the Acuitas Option Agreement, consisting of technology access fees, target reservation and maintenance fees, the costs of services performed by Acuitas, the material costs and the reimbursable costs.

Unless earlier terminated, the Acuitas Option Agreement will remain in effect until the first to occur of (1) both options being exercised, and (2) three years from the effective date, except that we can choose to extend the three year term for an additional two years. Either party may terminate the Acuitas Option Agreement for an uncured material breach of the other party or upon the other party's bankruptcy or a similar event. We may terminate the Acuitas Option Agreement at our convenience following written notice to Acuitas. The last to expire patent under the Acuitas Option Agreement, if issued, is expected to expire in 2041.

### *License Agreement*

In March 2021, we exercised the first option under the Acuitas Option Agreement and entered into a non-exclusive license agreement with Acuitas, or the Acuitas License Agreement. In connection with the execution of the Acuitas License Agreement, we incurred an expense of \$1.5 million for the option exercise fee. Acuitas granted us a non-exclusive, worldwide, sublicensable license under the Acuitas LNP Technology to research, develop, manufacture, and commercially exploit products consisting of our OTX-2002 gene modulating therapeutics and Acuitas's LNPs. The last to expire patent under the Acuitas License Agreement, if issued, is

expected to expire in 2041. Under the Acuitas License Agreement, we are required to pay Acuitas an annual license maintenance fee in the high six figures until we achieve a particular development milestone. Acuitas is entitled to receive potential clinical, regulatory, and commercial milestone payments of up to \$18.0 million in the aggregate. With respect to the sale of each licensed product by us, our affiliates or our sublicensees, Acuitas is entitled to receive low single digit percentage royalties on net sales of the licensed product in a given country until the last to occur, in such country, of (i) the expiration or abandonment of all licensed patent rights covering the licensed product, (ii) expiration of any regulatory exclusivity for the licensed product, or (iii) ten years from the first commercial sale of the licensed product, or Royalty Term. We are entitled to certain royalty reductions and offsets with respect to each licensed product in a given country if no licensed patents cover the licensed product or if we are required to obtain rights to third party patents that relate to LNP technology.

Unless earlier terminated, the Acuitas License Agreement will remain in effect until the expiration of the last-to-expire Royalty Term. Either party may terminate the Acuitas License Agreement for an uncured material breach of the other party upon the other party's bankruptcy or a similar event. We may terminate the Acuitas License Agreement at our convenience following written notice to Acuitas.

### **Government Regulation**

We are subject to extensive regulation. We expect our product candidates to be regulated as biologics. Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products.

#### ***U.S. biological products development process***

The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical laboratory tests, and preclinical animal trials and applicable requirements for the humane use of laboratory animals and formulation studies in accordance with applicable regulations, including good laboratory practices, or GLPs;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice, or GCP, regulations and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.



The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

In addition to the IND submission process, sponsors of certain human clinical trials of cells containing recombinant or synthetic nucleic acid molecules, including human gene transfer studies, are subject to evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution, pursuant to the National Institutes of Health's Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. The IBC assesses the safety of the research and identifies any potential risk to the public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical study must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the

FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

### ***U.S. review and approval process***

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act, or FDASIA, requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth

substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the applicant interprets the same data. If the FDA decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in 10 months from the filing date and 90% of priority BLAs in six months from the filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

### ***Orphan drug designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug or biologic was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

### ***Expedited development and review programs***

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, 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 designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product candidate is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For new-molecular-entity NDAs and original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical

benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, the FDA established a new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug or biologic that meets the following criteria: (i) the drug or biologic qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the drug or biologic is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug or biologic has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

### ***Post-approval requirements***

Biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and 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 cGMP, which impose certain procedural and documentation requirements up. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw 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 studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;

- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

### ***Biosimilars and exclusivity***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its 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.

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

### ***Government regulation outside of the United States***

Our product candidates will be subject to similar laws and regulations imposed by jurisdictions outside of the United States, and, in particular, the European Union, or EU, which may include, for instance, clinical trials, marketing authorization, post-marketing requirements, including safety surveillance, anti-fraud and abuse laws

and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. In addition, ethical, social and legal concerns about gene-editing technology, gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product candidates in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### **Non-clinical studies and clinical trials**

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both *in vitro* and *in vivo*, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products, or ATMPs. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before

January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

### **Marketing Authorization**

In order to market our future product candidates in the EU, and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of an investigational chemical or biological product under EU regulatory systems, we must submit a marketing authorization application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- “Centralized MAs” are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Product for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is mandatory for certain types of product candidates, such as (i) medicinal product derived from biotechnology processes, such as genetic engineering, (ii) designated orphan medicinal product, (iii) ATMPs such as gene therapy, somatic cell therapy or tissue-engineered medicines and (iv) medicinal product containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT’s opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT’s draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.
- “National MAs” are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the above described procedures, the EMA or the competent authorities of the EU member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Under the centralized procedure and in exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical



need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the Priority Medicines, or PRIME, scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. 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 MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

MAAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

*Data and marketing exclusivity.* In the EU, new product candidates authorized for marketing, or reference product candidates, generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The overall 10-year market exclusivity period may be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

## ***Pediatric development***

In the EU, MAAs for new medicinal product candidates not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. 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 PDCO can grant a deferral 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. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for a six-month supplementary protection certificate extension or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity is granted.

## ***Orphan Medicinal Products***

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. In the EU, a medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically-debilitating condition; (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

In the EU, an application for designation as an orphan product must be submitted before the MAA. Orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means during this period, the regulatory authorities cannot accept another MAA, or grant an MA or accept an application to extend an MA, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity 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 which it received orphan drug designation, including where the prevalence of the condition has increased above the threshold or it is judged that the product is sufficiently profitable not to justify maintenance of market exclusivity. Granting of an authorization for another similar orphan medicinal product can happen at any time if: (i) the second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior, (ii) the applicant cannot supply sufficient quantities of the orphan medicinal product or (iii) where the applicant consents to a second orphan medicinal product application. A company may voluntarily remove a product from the orphan register.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production,

distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

### ***Brexit and the Regulatory Framework in the United Kingdom***

The United Kingdom, or UK, left the EU on January 31, 2020, following which existing EU medicinal product legislation continued to apply in the UK during the transition period under the terms of the EU-UK Withdrawal Agreement. The transition period, which ended on December 31, 2020, maintained access to the EU single market and to the global trade deals negotiated by the EU on behalf of its members. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was then crystallized in the Trade and Cooperation Agreement, or TCA, and became effective on the January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as “retained EU law”. However, new legislation such as the EU CTR will not be applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an ‘appropriate authority’ to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK’s standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules will apply in Northern Ireland than in England, Wales, and Scotland, together, Great Britain, or GB; broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA. The MHRA has published a guidance on how various aspects of the UK regulatory regime for medicines will operate in GB and in Northern Ireland following the expiry of the Brexit transition period on December 31, 2020. The guidance includes clinical trials, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the UK. The new guidance was given effect via the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019, or the Exit Regulations.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder chooses to opt-out. In order to use the centralized procedure to obtain a MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to use the centralized procedure to obtain a MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. The MHRA may rely on a decision taken by the European Commission on the approval of a new (centralized procedure) MA when determining an application for a GB authorization; or use the MHRA’s decentralized or mutual recognition procedures which enable MAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in GB.

There will be no pre-MA orphan designation. Instead, the MHRA will review applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in GB, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in GB.

## **Other Healthcare Laws**

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and transparency laws and regulations with respect to drug pricing and payments and other transfers of value made to physicians and other health care providers. Violations of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations to resolve allegations of noncompliance, exclusion from participation in federal and state healthcare programs and imprisonment.

## **Coverage and Reimbursement**

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

The U.S. government, state legislatures and foreign governments have also continued implementing cost-containment programs, including price controls, restrictions on coverage and 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 sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

## **Healthcare Reform**

In the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA

brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which was temporarily suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could impact the amounts that federal and state governments and other third-party payors will pay for healthcare products and services.

### ***Data Privacy & Security***

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. As our operations and business grow, we may become subject to or affected by U.S. federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA, that govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain state and non-U.S. laws, such as the European Union General Data Protection Regulation, or GDPR, govern the privacy and security of personal data, including health-related data, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

### **Employees**

As of December 31, 2021, we had 79 full-time employees and 1 part-time employee.

### **Corporate Information**

We were incorporated under the laws of the State of Delaware in July 2016 under the name VL42, Inc.

## Item 1A. Risk Factors.

*You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K, in evaluating our company. If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, and the trading price of our common stock could decline. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.*

### **Risks Related to Our Financial Condition and Capital Requirements**

***We have a limited operating history and no history of successfully developing or commercializing any approved product candidates, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.***

We are a development-stage biopharmaceutical company. Our operations to date have been limited to financing and staffing our company, developing our technology and identifying and developing our product candidates. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by biopharmaceutical companies in their early stages of operations. We have not yet demonstrated an ability to conduct or complete any clinical trials, obtain marketing approval, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for, and commercializing product candidates. In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other obstacles.

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

***We have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future.***

We have incurred significant net losses since our inception, including net losses of \$68.3 million and \$29.4 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of \$134.5 million. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our preclinical development activities and preparing for clinical trials of our product candidates.

We expect to continue to incur significant additional net losses for the foreseeable future as we seek to advance product candidates through clinical development, continue preclinical development, expand our research and development activities, develop new product candidates, complete preclinical studies and clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. In order to obtain United States Food and Drug Administration, or FDA, approval to market any product candidate in the United States, we must submit to the FDA a Biologics License Application, or BLA, demonstrating to the FDA's satisfaction that the product candidate is safe and effective for its intended use(s). Foreign regulatory authorities impose similar requirements. This demonstration requires significant research and extensive data from animal tests, which are referred to as nonclinical or preclinical studies, as well as human tests, which are referred to as clinical trials. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial and difficult to accurately predict. Because of the numerous risks and uncertainties associated with the development of drug products, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. Our expenses will also increase substantially if or as we:

- continue our research and development efforts and submit INDs, or similar foreign applications, for our product candidates;
- initiate and conduct clinical trials of our product candidates;
- continue to engineer and develop additional product candidates;
- continue to develop the OMEGA platform;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical trials, if any;
- establish manufacturing and supply chain capacity sufficient to provide clinical and, if applicable, commercial quantities of product candidates, including building our own manufacturing facility;
- establish a sales, marketing, internal systems and distribution infrastructure to commercialize any products for which we may obtain regulatory approval, if any, in geographies in which we plan to commercialize our products ourselves;
- maintain, expand, protect and enforce our intellectual property estate;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial, and support personnel, to execute our business plan and support our product development and potential future commercialization efforts;
- enter into collaborations or licenses for new technologies;
- make royalty, milestone, or other payments under our current and any future in-license agreements;
- incur additional legal, accounting, and other expenses in operating our business; and
- continue to operate as a public company.

The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no commercial-stage products, will not generate revenues from the commercial sale of products until we have successfully developed one or more product candidates, and might never generate revenues from the sale of products. We expect to continue to incur operating losses and negative cash flows for the foreseeable future. These operating losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

***We require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce, or terminate our product development.***

Our operations have incurred substantial expenses since inception. We expect to continue to incur substantial expenses to continue the preclinical development and to initiate and conduct the clinical development of our product candidates, and to continue to identify new product candidates.

We continue to need additional capital beyond the proceeds of our IPO to fund our planned preclinical development and clinical trials, and to develop new product candidates, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources. Additional sources of financing might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to initiate or complete clinical trials, or seek regulatory approvals, of any of our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

The net proceeds from our IPO and our existing cash, cash equivalents and marketable securities as of December 31, 2021 will not be sufficient to fund all of our efforts that we plan to undertake. Based on our current operating plan, we believe that the net proceeds from the IPO, together with our cash, cash equivalents and marketable securities as of December 31, 2021, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this Annual Report. This estimate

is based on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We will require significant additional funds in order to launch and commercialize our current and any future product candidates. In addition, other unanticipated costs may arise in the course of our development efforts. Because all of our product candidates are in preclinical development and we have not conducted any clinical trials, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results, and costs of our preclinical studies and any future clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for our current and future product candidates in regions where we choose to commercialize any products;
- the number of future product candidates and potential additional indications that we may pursue and their development requirements;
- the stability, scale, yield, and cost of our manufacturing process as we scale-up production and formulation of our product candidates for clinical trials, in preparation for regulatory approval and in preparation for commercialization, including our ability to build our own manufacturing facility;
- the costs of pre- and post-commercialization activities for any approved product, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities;
- revenue, if any, received from commercial sales of our products, should any of our product candidates receive marketing approval;
- the costs and timing of changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs and timing of changes in the regulatory environment and enforcement rules;
- our ability to compete with other therapeutics in the indications we target;
- the effect of competing technological and market developments;
- the extent to which we enter into collaborations or licenses for products, product candidates, or technologies;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the costs of preparing, filing, and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims;
- the costs of operating as a public company; and
- the severity, duration, and impact of the COVID-19 pandemic, which may adversely impact our business.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, on terms acceptable to us, or on a timely basis, we may have to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or other research and development initiatives.

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

***Raising additional capital may cause additional dilution to our stockholders, restrict our operations, require us to relinquish rights to our technologies or product candidates, and could cause our share price to fall.***



Until such time, if ever, as we can generate substantial revenue from product sales, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations, our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, redeeming our stock, making certain investments, and engaging in certain merger, consolidation, or asset sale transactions, among other restrictions. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, or product candidates or 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.

***Our existing and any future indebtedness could adversely affect our ability to operate our business.***

As of December 31, 2021, we had \$20.0 million of outstanding borrowings under an amended loan and security agreement, the Loan Agreement, with Pacific Western Bank, or PWB. The maturity date of the Loan Agreement is September 30, 2025, and we will be required to begin repayment of the loan in 24 equal monthly payments beginning on September 30, 2023. The outstanding balance under the Loan Agreement bears interest at a floating annual rate equal to the greater of (i) 0.50% above the prime rate then in effect and (ii) 5.50%, due monthly starting the first month after December 20, 2021. Pursuant to the terms of the Loan Agreement, interest payment on the outstanding term loan is less than \$0.1 million per month, and we are required to pay a success fee of up to \$0.2 million upon the occurrence of a specified liquidity event. Our outstanding indebtedness, including any additional indebtedness beyond our borrowings from PWB, combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product candidate development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our then existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under the Loan Agreement or any other debt instruments. Failure to make payments or comply with other covenants under the Loan Agreement or such other debt instruments could result in an event of default and acceleration of amounts due. For example, the affirmative covenants under our Loan Agreement include, among others, covenants requiring us (and us to cause our subsidiaries) to maintain our legal existence and governmental approvals, deliver certain financial reports and notifications, maintain proper books of record and account, timely file and pay tax returns, maintain inventory and insurance coverage, and maintain cash with PWB (subject to exceptions) and in accounts subject to control agreements (subject to exceptions). Under the Loan Agreement, the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, assets or condition is an event of default. If an event of default occurs and PWB accelerates the amounts due, we may not be able to make accelerated payments and the lender could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under the Loan

Agreement, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

***We have not generated any product revenue and may never be profitable.***

Our ability to become profitable depends upon our ability to generate product revenue. To date, we have not generated any product revenue and do not expect to generate significant product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, our product candidates. All of our product candidates are in the preclinical stages of development and will require additional preclinical studies and clinical development, regulatory review and approval, a secure manufacturing supply, established sales capabilities for commercialization, substantial investment and sufficient funds, and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate product revenue depends on a number of factors, including:

- our ability to complete IND-enabling or other clinical trial-enabling studies and successfully submit INDs or comparable applications to allow us to initiate clinical trials of our product candidates;
- timely initiation and completion of any clinical trials of our product candidates, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates;
- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety and efficacy of our product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics, and patients to utilize or adopt epigenetic therapeutics;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities, and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP, or similar regulatory requirements outside the United States;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates, whether alone or in collaboration with others; and
- our ability to establish, maintain, protect, and enforce intellectual property rights in and to our product candidates.

Many of the factors listed above are beyond our control, and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates, we may be unable to continue operations without continued funding.

**Risks Related to the Discovery, Development, Preclinical and Clinical Testing, and Regulatory Approval of Our Product Candidates**

***Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of preclinical and clinical development and of subsequently obtaining regulatory approval, if at all.***

Our success depends on the OMEGA platform technology which is a novel technology. As such, it is difficult to accurately predict the preclinical and clinical developmental challenges we may incur for our programs and product candidates as they proceed through product discovery or identification, preclinical studies, and clinical trials. In addition, because we have not commenced clinical trials of any of our pipeline product candidates, we have not yet been able to assess the safety or efficacy of our technology in humans and there may be short-term or long-term effects from treatment with any product candidates that we develop that we cannot predict at this time. Also, animal models may not exist for some of the diseases we choose to pursue in our programs. Given the novelty of our technology platform, there can be no assurance as to the length of preclinical work, clinical development, the number of patients that FDA or comparable foreign regulatory authority may require to be enrolled in clinical trials to establish the safety and efficacy, purity and potency of our product candidates, or that the data generated in these clinical trials will be acceptable to the FDA or comparable foreign regulatory authorities to support marketing approvals. The FDA and comparable regulatory authorities may take longer than usual to come to a decision on any biologics license application, or BLA, or foreign marketing application, that we submit and may ultimately determine that there is not adequate data, information, or experience with our product candidate to support approval. The FDA or comparable foreign regulatory authorities may also require that we conduct additional post-marketing studies or implement risk management programs, such as a risk evaluation and mitigation strategy, or REMS, or similar risk management measures, until more experience with our product candidates are obtained. Each of these factors could increase our expected development costs, and delay, prevent, or limit the scope of any commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone, or in combination with other therapies.

Moreover, even if we obtain data from our planned clinical trials, because the OMEGA platform technology applied in our programs is novel and has not been externally verified, our data may be difficult to replicate and/or subject to misinterpretation by us or others. Epigenomic controllers present a new class of medicines and have not been evaluated in clinical trials or received regulatory approval. As a result, we may need to develop new evaluation methods or metrics for clinical data, which may make it more difficult to analyze data, or it may take more time or be more costly for us to develop our OECs than other therapeutics for the same indications. As a result of these factors, it is difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of the OMEGA platform technology, or any similar or competitive epigenetic technologies, will result in the identification, development, and regulatory approval of any products. There can be no assurance that any development challenges we experience in the future related to the OMEGA platform technology or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. 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 may develop on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA 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 as well as 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 extensively studied therapeutic modalities and approaches. Further, as we are developing novel treatments, there is heightened risk that the FDA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, few gene therapy products have been approved by the FDA and comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union, or EU, or other jurisdictions. Further, approvals by one regulatory authority may not be indicative of what other regulatory authorities may require for approval.

Regulatory requirements governing programmable epigenetic medicines have evolved and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In addition to FDA oversight and oversight by IRBs, under guidelines promulgated by the National Institutes of Health, or NIH, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety

committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical study can begin at any institution, that institution's IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. These and other regulatory review agencies, committees, and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. Similar requirements apply in the EU. The European Medicines Agency, or the EMA, has a Committee for Advanced Therapies, or CAT, that is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products, or ATMP(s). ATMPs include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for ATMP candidate that is submitted to the EMA. In the EU, the development and evaluation of an ATMP must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape.

Changes in applicable regulatory guidelines may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates, or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with regulatory authorities and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

***No epigenomic controller medicines have been approved in this potentially new class of medicines, and may never be approved as a result of efforts by others or us. mRNA drug development has substantial development and regulatory risks due to the novel and unprecedented nature of this new category of medicines.***

As a potential new category of medicines, no epigenomic controller medicines have been approved to date by the FDA or other regulatory authority. Successful discovery and development of epigenomic controller medicines by either us or our strategic collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. We have made and will continue to make a series of business decisions and take calculated risks to advance our development efforts and pipeline, including those related to mRNA technology, delivery technology, and manufacturing processes which may be shown to be incorrect based on further work by us, our strategic collaborators, or others.

Our medicines that appear promising in the early phases of development may fail to advance, experience delays in preclinical stages or the clinic, experience clinical holds, or fail to reach the market for many reasons, including:

- discovery efforts at identifying potential epigenomic controller medicines may not be successful;
- nonclinical or preclinical study results may show potential epigenomic controller medicines to be less effective than desired or to have harmful or problematic side effects;

- clinical trial results may show the epigenomic controller medicines to be less effective than expected (e.g., a clinical trial could fail to meet one or more endpoints) or to have unacceptable side effects or toxicities;
- adverse effects in any one of our preclinical studies or clinical trials or adverse effects relating to our mRNA, or lipid nanoparticles, or LNPs, may lead to delays in or termination of one or more of our programs; and
- the insufficient ability of our translational models to reduce risk or predict outcomes in humans, particularly given that each component of our investigational medicines and development candidates, may have a dependent or independent effect on safety, tolerability, and efficacy, which may, among other things, be species-dependent.

Our investigational medicines are currently formulated and administered in an LNP. These LNPs may cause systemic side effects related to the components of the LNP and some may have not yet been tested in humans. A recognized limitation of LNPs is the potential for inflammatory reactions upon single and repeat administration that can impact tolerability and therapeutic index. Our licensed and internally developed, proprietary LNP systems are therefore designed to be highly tolerated and minimize LNP vehicle-related toxicities with repeat administration *in vivo*. While we continue to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within biological pathways or due to degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our preclinical or clinical studies. Our LNPs could contribute, in whole or in part, to one or more of the following: immune reactions, infusion reactions, complement reactions, opsonation reactions, antibody reactions including IgA, IgM, IgE or IgG or some combination thereof, or reactions to the polyethylene glycol, or PEG, from some lipids or PEG otherwise associated with the LNP. Many of these types of side effects have broadly been observed for LNPs. There may be resulting uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in future clinical trials and would result in significant delays in our programs.

***Preclinical development is uncertain, especially for a new class of medicines such as epigenomic controllers, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance into the clinic, any of which may have a material adverse impact on our platform or our business.***

All of our programs are in preclinical development and we have identified only one lead development candidate to date. Before we can initiate clinical trials for a development candidate, we must complete extensive preclinical studies, including IND-enabling good laboratory practices, or GLP, and equivalent requirements outside the United States, toxicology testing. Preclinical development is uncertain, including due to variability in the disease models used. We may not identify development candidates with the treatment activity or safety characteristics required to advance them into further preclinical studies or results from preclinical studies of initially promising development candidates may not support further testing. We must also complete extensive work on Chemistry, Manufacturing, and Controls, or CMC, activities (including yield, purity and stability data) to be included in any IND or similar foreign filing. CMC activities for a new class of medicines such as epigenomic controllers require extensive manufacturing processes and analytical development, which is uncertain and lengthy. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies, and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to

demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, time-consuming, and subject to uncertainty. A failure of one or more clinical trials can occur at any stage of the process, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

To date, we have not initiated or completed any clinical trials for any of our product candidates. We cannot guarantee that any of our clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of any future IND or similar application will result in the FDA or other regulatory authority, as applicable, allowing future clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on trial design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- delays in obtaining required institutional review board, or IRB, or ethics committee approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing, or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- delays in recruiting, screening, and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, clinical sites, other third parties or us to adhere to clinical trial protocols, to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements, or GCPs, or similar applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites dropping out of a trial;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract development and manufacturing organization, or CDMO, and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. Clinical trial delays could also shorten any periods during which any approved products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

Clinical trials must be conducted in accordance with the legal requirements, regulations, or guidelines of the FDA and other applicable regulatory authorities, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board, or DSMB, for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, which could significantly reduce the commercial viability of our

product candidates. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

It is currently unclear to what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closes on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted

***The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, expensive, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be seriously harmed.***

We are not permitted to commercialize, market, promote, or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate in the United States or any other jurisdiction, and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval.

Prior to obtaining approval to commercialize a product candidate in the United States or elsewhere, we must demonstrate with substantial evidence from well-controlled trials, and to the satisfaction of the FDA, or other regulatory authorities, that such product candidates are safe and effective, pure, and potent for their intended uses. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA or other regulatory authorities. The FDA or other regulatory



authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

The FDA or any foreign regulatory authorities can delay, limit, or deny approval of our product candidates, or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including, but not limited to, the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation, or interpretation of results of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective, pure, and potent for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required for approval by the FDA or comparable foreign regulatory authorities;
- serious and unexpected product candidate-related side effects experienced by participants in our clinical trials or by individuals using products similar to our product candidates;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or other submission, or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree regarding the formulation, labeling, and/or the specifications of our product candidates;
- our clinical sites, investigators or other participants in our clinical trials may deviate from a trial protocol, fail to conduct the trial in accordance with regulatory requirements, or drop out of a trial;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business.

Even if we eventually complete clinical trials and obtain approval of a BLA or foreign marketing application for our product candidates, the FDA, or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional trials, including Phase 4 clinical trials, and/or the implementation of a REMS or similar risk management measures, which may be required to ensure the benefits of the drug outweigh its risks after approval. The FDA or comparable foreign regulatory authorities may also approve a product candidate for a more limited indication or patient population than we originally requested. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate, and would materially adversely impact our business and prospects.

***Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.***

Adverse events or other undesirable side effects caused by our product candidates could cause us, any DSMB for a trial, or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory

authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer, and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts, and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval.

If any serious adverse events occur during clinical development, clinical trials of any product candidates or products we develop could be suspended or terminated, and our business could be seriously harmed. Treatment-related side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, or deny approval of any product candidates for any or all targeted indications. If we are required to delay, suspend, or terminate any clinical trial, the commercial prospects of such product candidates may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated.

Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit, or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS or similar risk management measures which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions, or the imposition of criminal penalties;
- 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 the particular product candidate, if approved, and could seriously harm our business.

***Our company has never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.***

We have never obtained regulatory approval for, or commercialized any product candidate. It is possible that the FDA may refuse to accept any or all of our planned BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned BLAs, it may require that we conduct additional costly clinical trials, preclinical studies or CMC studies before it will reconsider our applications. Depending on the extent of these or any other FDA- required studies, approval of any BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any

failure or delay in obtaining regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any BLA or other application that we submit. Similar risks may exist in foreign jurisdictions. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

***If we encounter difficulties enrolling patients in any clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the target disease population;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- competing clinical trials for similar therapies or other new therapeutics not involving our product candidates and or related technologies;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before trial completion; and
- other factors outside of our control, such as the COVID-19 pandemic.

In addition, our planned clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or similar areas, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

***Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different

conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

***We may not be successful in our efforts to identify and successfully develop additional product candidates.***

Part of our strategy involves identifying novel product candidates. The OMEGA platform may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third-parties' patent or other intellectual property or exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance, if approved;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

***We have invested, and expect to continue to invest, in research and development efforts that further enhance the OMEGA platform. Such investments may affect our operating results, and, if the return on these investments is lower or develops more slowly than we expect, our revenue and operating results may suffer.***

We use our technological capabilities for the discovery of new product candidates and, since our inception, we have invested, and expect to continue to invest, in research and development efforts that further enhance the OMEGA platform. These investments may involve significant time, risks, and uncertainties, including the risk that the expenses associated with these investments may affect our margins and operating results and that such investments may not generate sufficient technological advantages relative to alternatives in the market, which would in turn, impact revenues to offset liabilities assumed and expenses associated with these new investments. The software industry changes rapidly as a result of technological and product developments, which may render our platform's ability to identify and develop product candidates less efficient than other technologies and platforms. We believe that we must continue to invest a significant amount of time and resources in the OMEGA platform to maintain and improve our competitive position. If we do not achieve the benefits anticipated from these investments, if the achievement of these benefits is delayed, or if our technology is not able to accelerate the process of drug discovery as quickly as we anticipate, our revenue and operating results may be adversely affected.

***We must adapt to rapid and significant technological change and respond to introductions of new products and technologies by competitors to remain competitive.***

In addition to using our platform for the discovery and development of our own product candidates, we collaborate with other biopharmaceutical and pharmaceutical companies in the discovery and development of our OEC. The technological landscape around artificial intelligence and precision drug design is characterized by significant enhancements and evolving industry standards. As a result, our and our collaborators' needs are rapidly evolving. If we do not appropriately innovate and invest in new technologies, our platform may become less competitive, and our collaborators could move to new technologies offered by our competitors, or engage in drug discovery themselves. We believe that because of the initial time investment required by many of our collaborators to reach a decision about whether to collaborate with us, it may be difficult to regain a commercial relationship with such collaborator should they enter into a partnership or collaboration agreement with a competitor. Without the timely introduction of new solutions and technological enhancements, our offerings will likely become less competitive over time, in which case our competitive position and operating results could suffer. Accordingly, we focus significant efforts and resources on the development and identification of new technologies and markets to further broaden and deepen our capabilities and expertise in drug discovery and development. For example, to the extent we fail to timely introduce new and innovative technologies or solutions, adequately predict our collaborators' needs or fail to obtain desired levels of market acceptance, our business may suffer and our operating results could be adversely affected.

***The potential market opportunities for our product candidates may be smaller than we anticipated or may be limited to those patients who are ineligible for or have failed prior treatments, and our estimates of the prevalence of our target patient populations may be inaccurate.***

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of cancers that may be addressable by our product candidates, which is derived from a variety of sources, including scientific literature and surveys of clinics. Our projections may prove to be incorrect and the number of potential patients may turn out to be lower than expected. Even if we obtain significant market share for our product candidates, because the potential target populations could be small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use of our product candidates for front-line and second-line therapy.

Cancer therapies are sometimes characterized by line of therapy (first-line, second-line, third-line, etc.), and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first-line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second-line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third-line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of some of our product candidates as second- or third-line therapies for patients who have failed other approved treatments. Subsequently, for those product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second-line therapy and potentially as a first-line therapy, but there is no guarantee that our drug candidates, even if approved for third-line therapy, would be

approved for second-line or first-line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second-line or first-line therapy.

***We may focus on potential product candidates that may prove to be unsuccessful and we may have to forego opportunities to develop other product candidates that may prove to be more successful.***

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

Furthermore, we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidates, and as such, we may forego or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates 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 future product candidates.

***We may pursue fast track, breakthrough, and regenerative medicine advanced therapy designation by FDA. These designations may not actually lead to a faster development or regulatory review or approval process, and they do not assure FDA approval of any product candidates we may develop.***

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

***Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review

periods. Seeking foreign regulatory approvals could result in significant delays, difficulties, and costs for us and may require additional preclinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain, and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

***Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.***

If any current or future product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA and foreign regulatory authorities to review or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA, following its relocation to Amsterdam and related reorganization (including staff changes), may also slow 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 FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The

FDA utilized this risk-based assessment system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the U.S. have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities, which could have a material adverse effect on our business. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, property, auto, employment practices, workers' compensation, environmental liability, and directors' and officers' insurance.

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. Although our environment liability insurance provides certain coverage for claims attributable to the release of biological or hazardous materials, our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Operating as a public company has and will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

#### **Risks Related to Healthcare Laws and Other Legal Compliance Matters**

***We will be subject to extensive and costly government regulation.***

Our product candidates will be subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective equivalents outside of the United States. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. If our



products are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We must obtain and maintain regulatory authorization to conduct preclinical studies and clinical trials. We must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy, potency, and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our consultants, CDMOs, CROs, or other vendors, fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA or other regulatory authorities, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

***Enacted and future healthcare legislation and policies may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and could adversely affect our business.***

In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could prevent or delay marketing approval of our products in development, restrict or regulate post-approval activities involving any product candidates for which we obtain marketing approval, impact pricing and reimbursement and impact our ability to sell any such products profitably. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted.

In March 2010, the Patient Protection and Affordable Care Act, or ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect as of the date of this report through 2030, unless additional Congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as outcomes-based reimbursement. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could

harm our business, results of operations, financial condition and prospects. In addition, regional healthcare 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 healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the EU, similar political, economic, and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. EU member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. EU member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval in some EU member states, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care. Other EU member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. Generally, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict, or regulate post-approval activities, and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In addition, in the United States, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU, or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

***If our product candidates obtain regulatory approval, we and they will be subject to ongoing regulatory review and significant post-market regulatory requirements and oversight.***

If the FDA or other regulatory authorities approve any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and record-keeping of our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and similar foreign requirements and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of biological products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities to ensure compliance with cGMP regulations and similar standards. If we or a regulatory authority

discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, any regulatory approvals that we may receive for our product candidates may contain significant limitations related to use restrictions for specified age groups, warnings, precautions, or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training, and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools.

Failure to comply with applicable regulatory requirements, may subject us to administrative or judicially imposed sanctions, including:

- delays in reviewing or the rejection of product applications or supplements to approved applications;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- warning or untitled letters;
- civil or criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions, or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on our operations, including costly new manufacturing requirements.

The occurrence of any such event may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

Moreover, the policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***The Hatch-Waxman Act in the United States provides for the opportunity to seek a patent term extension on one selected patent for each of our products, and the length of that patent term extension, if at all, is subject to review and approval by the U.S. Patent and Trademark Office, or the USPTO, and the FDA.***

In the United States, the Hatch-Waxman Act permits one patent term extension of up to five years beyond the normal expiration of one patent per product, which if a method of treatment patent, is limited to the approved indication (or any additional indications approved during the period of extension). The length of the patent term extension is typically calculated as one half of the clinical trial period plus the entire period of time during the review of the BLA by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. Therefore, if we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable

authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate product revenue.

In 1997, as part of the Food & Drug Administration Modernization Act, or FDAMA, Congress enacted a law that provides incentives to drug manufacturers who conduct studies of drugs in children. The law, which provides six months of exclusivity in return for conducting pediatric studies, is referred to as the pediatric exclusivity provision. If clinical studies are carried out by us that comply with the FDAMA, we may receive an additional six-month term added to any regulatory data exclusivity period and our patent term extension period, if received, on our product. However, if we choose not to carry out pediatric studies that comply with the FDAMA, or are not accepted by the FDA for this purpose, we would not receive this additional six-month exclusivity extension to our data exclusivity or our patent term extension.

In the EU, supplementary protection certificates, or SPCs, are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and can be extended (if any is in effect at the time of approval) for an additional six months if data from clinical trials is obtained in accordance with an agreed-upon pediatric investigation plan. Although all EU member states must provide SPCs, SPCs must be applied for and granted on a country-by-country basis. This can lead to a substantial cost to apply for and receive these certificates, which may vary among countries or not be granted at all.

***Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which makes it illegal for any person to knowingly and willfully solicit, offer, receive, pay, or provide any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false, fictitious, or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Companies that submit claims directly to payors may also be liable under the FCA for the direct submission of such claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or

should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the Federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our product candidates, if approved, may not comply with current or future statutes, regulations, agency guidance, 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight, and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, 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 not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security. Our actual or perceived failure to comply with such obligations could harm our business.***

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the EU and the European Economic Area, or EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland), the GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. For example, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers, increases the privacy and security obligations of entities handling certain personal information, requires certain disclosures to California individuals, affords such individuals new abilities to opt out of certain sales of personal information, and provides for civil penalties for violations as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or another third party, could adversely affect our business, financial condition, and results of operations, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive, and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services, and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. For example, on May 25, 2018, the GDPR went into effect and imposes strict requirements for processing the personal data of individuals within the EEA. For example, the GDPR applies extraterritorially, requires us to make detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, requires us to obtain valid consent for collecting and processing personal data (including data from clinical trials), requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides robust rights for data subjects, imposes mandatory data breach notification, imposes certain obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training, and data audit. The GDPR provides that EEA countries may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States. For example, in 2016, the EU and United

States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union, or CJEU. While the CJEU upheld the adequacy of the standard contractual clauses, or SCC, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the SCCs cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. The revised SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the United Kingdom's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021.

Additionally, from January 2021, we have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million (£17.5 million) or 4% of global turnover for violations. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and remains under review by the Commission during this period. In September 2021, the United Kingdom government launched a consultation on its proposals for wide-ranging reform of United Kingdom data protection laws following Brexit. These changes may lead to additional costs and increase our overall risk exposure. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations, and financial condition.

We cannot assure you that our CDMOs, CROs or other third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage, and transmission of such information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. If we or third-party CDMOs, CROs, or other contractors or consultants fail to comply with applicable federal, state, or local regulatory privacy requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing, and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security, or reputational damage. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.***



Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws, and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures, and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

***We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.***

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with applicable laws and regulations, our policies, and other legal or contractual requirements, which may give rise to regulatory enforcement action, liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, financial condition, and results of operations, and could adversely affect the price of our common stock.

### **Risks Related to Commercialization**

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

We are very early in our development efforts and have focused our research and development efforts to date on developing the OMEGA platform, identifying our initial targeted disease indications and engineering our initial OECs. We have only conducted *in vivo* preclinical studies for some of our programs and there is no guarantee that we will conduct preclinical *in vivo* studies for other programs. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of our product candidates, which may never occur.

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

Commercialization of our product candidates will require additional preclinical and clinical development and regulatory and marketing approval. Our ability to conduct development or attain marketing approval will depend

on the sufficiency of our financial and other resources to complete the necessary preclinical studies, IND-enabling studies or similar studies, and clinical trials and the successful enrollment in, and completion of, clinical trials.

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

***Developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets.***

Our industry has been characterized by extensive research and development efforts, rapid developments in technologies, intense competition, and a strong emphasis on proprietary products. We expect our product candidates to face intense and increasing competition as new products enter the relevant markets and advanced technologies become available. We face potential competition from many different sources, including pharmaceutical, biotechnology, and specialty pharmaceutical companies. Academic research institutions, governmental agencies, and public and private institutions are also potential sources of competitive products and technologies. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Many of these competitors may also have compounds already approved or in development in the therapeutic categories that we are targeting with our product candidates. In addition, many of these competitors, either alone or together with their collaborators, may operate larger research and development programs or have substantially greater financial resources than we do, as well as greater experience in:

- developing product candidates;
- undertaking preclinical testing and clinical trials;
- obtaining BLA approval by the FDA or comparable foreign regulatory approvals of product candidates;
- formulating and manufacturing products; and
- launching, marketing, and selling products.

If these competitors access the marketplace before we do with safer, more effective, or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products, or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing, and selling commercial quantities of potential products.

While we are not aware of other companies developing epigenomic controllers, we compete with many companies that are using other technologies targeting the same indications we are currently pursuing. We expect our product candidates to compete with companies developing technologies that focus on gene-expression control using various technologies, such as CRISPR gene editing, gene therapies, non-coding RNA therapeutics, and small-molecule epigenetics, including Anylam Pharmaceuticals Inc., Beam Therapeutics, Inc., Biogen Inc., Constellation Pharmaceuticals, Inc., CRISPR Therapeutics AG, Editas Medicine, Inc., Epizyme, Inc., Intellia Therapeutics, Inc., Ionis Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., Pfizer Inc., and Sangamo Therapeutics, Inc. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians, or patients. Hospitals, physicians, or patients may conclude that our products are less safe or effective or otherwise less attractive than existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Many of our competitors have substantially greater capital resources, robust product candidate pipelines, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do.

As a result, our competitors may achieve product commercialization or patent or other intellectual property protection earlier than we can. 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 clinical, regulatory, scientific, sales, marketing, 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 noncompetitive.

***Our product candidates may face competition sooner than anticipated.***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing 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 its product.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

***The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.***

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs and biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Even if we show improved efficacy or improved convenience of administration with our product candidates,

pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program is increasingly used as a model for how private and other governmental payors develop their coverage and reimbursement policies for new drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Some third-party payors may require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in the EU and other jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

***If we are unable to establish sales, marketing, and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing any of our product candidates, if approved, and we may not be able to generate any product revenue.***

We have limited personnel or infrastructure for the sales, marketing, or distribution of products, and no experience as a company in commercializing a product candidate. The cost of building and maintaining such an organization may exceed the cost-effectiveness of doing so.

We may build our own focused sales, distribution and marketing infrastructure to market our product candidates, if approved, in the United States and other markets around the world. There are significant expenses and risks involved with building our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidate, if approved. Additionally, if the commercial launch of our product candidate for which we recruit a sales force and establish marketing 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 sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates 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 our future products;
- our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to develop or obtain sufficient operational functions to support our commercial activities; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable or decide not to establish internal sales, marketing, and distribution capabilities, or decide not to do so for a particular country, we may pursue collaborative arrangements. If we pursue a collaborative arrangement, our sales will largely depend on the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product.

If we are unable to build our own sales force or access a collaborative relationship for the commercialization of any of our product candidates, we may be forced to delay the potential commercialization of our product candidates or reduce the scope of our sales or marketing activities for such product candidates. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborators at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to any of our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results, and prospects.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our other product candidates and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

In addition, even if we do establish adequate sales, marketing, and distribution capabilities, the progress of general industry trends with respect to pricing models, supply chains, and delivery mechanisms, among other things, could deviate from our expectations. If these or other industry trends change in a manner which we do not anticipate or for which we are not prepared, we may not be successful in commercializing our product candidates or become profitable.

***Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future profitability may depend, in part, on our ability to commercialize our product candidates, if approved, in foreign markets, including the EU, for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries, we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval

of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities if we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting, and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- our ability to supply our product candidates on a timely and large-scale basis in local markets;
- longer lead times for shipping which may necessitate local manufacture of our product candidates;
- language barriers for technical training and the need for language translations;
- reduced protection of patent and other intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions, and changes in tariffs.

If any of our product candidates is approved for commercialization, we may selectively partner with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries, including requirements specific to biologics or gene therapy products;
- reduced protection for patent and other intellectual property rights;
- foreign reimbursement, pricing, and insurance regimes;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- political unrest and wars, such as the developing conflict between Russia and Ukraine, which could delay or disrupt business activity, and if such political unrest escalates or spills over to or otherwise impacts additional regions, it could heighten many of the other risk factors described in this Item 1A; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor, and other legal requirements imposed by both the EU and many of the individual EU member states with which we will need to comply. Many U.S.-based biotechnology companies have found the process of marketing their own products in the EU to be very challenging.

Certain legal and political risks are also inherent in foreign operations. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities, political unrest and wars, such as the developing conflict between Russia and Ukraine, and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political

conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition, or results of operations.

In some countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

***Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.***

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- injury to our reputation;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources, and the inability to commercialize any product candidate;
- decreased demand for a product candidate, if approved for commercial sale; and
- loss of revenue.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we plan to obtain clinical trial insurance, our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

**Risks Related to our Dependence on Third Parties and Manufacturing**

***Due to increased demand for the manufacture of mRNA- and LNP-based vaccines to treat COVID-19, our ability to manufacture our OEC candidates for preclinical or clinical supply could be limited, which could adversely affect our development plans.***

We rely on third-party CDMOs of mRNA therapeutics and lipid excipients, a lipid that serves as the vehicle or medium for a drug or other active substance, to manufacture our preclinical and clinical supply of our OEC candidates. Vaccines to treat COVID-19 include mRNA vaccines and vaccines that utilize lipid excipients. Several vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA, and more may be authorized in the coming months. As a result, there is unprecedented demand on these CDMOs to manufacture COVID-19 vaccines and capacity for non-COVID-19 vaccines is limited and may be further limited by the potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or manufacturing slots for the products needed for our planned clinical trials. While we are working to obtain sufficient supply of our OECs for our anticipated preclinical and clinical development, we may experience supply constraints and disruptions as manufacturers prioritize supply for COVID-19 vaccines over our OECs. If we are unable to obtain the supplies we need at a reasonable price or on a timely basis or in the amounts we desire, our ability to complete the development of our OEC candidates or, if we obtain regulatory approval for our OEC candidates, to commercialize them, could be materially adversely affected.

***Our OEC candidates are based on novel technology and may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management, or shipping.***

Due to the novel nature of our technology and limited experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. As a result, the preclinical or clinical development of our OEC candidates could be materially delayed or we could be required to begin a new study or trial with a newly formulated drug product.

The process to generate mRNA-encoded OEC candidates encapsulated in LNPs is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. Furthermore, we have not manufactured our OECs at commercial scale. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply.

As we continue developing manufacturing processes for our drug substance and drug product, the changes we implement to manufacturing process may in turn impact specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our preclinical studies or any clinical trials. Our OEC candidates may prove to have a stability profile that leads to a lower than desired shelf life of the final approved OEC, if any. This poses risk in supply requirements, wasted stock, and higher cost of goods.

Our product and product intermediates are extremely temperature sensitive, and we may learn that any or all of our products are less stable than desired. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our OEC candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions.

Our rate of innovation is high, which has resulted in and will continue to cause a high degree of technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of new manufacturing infrastructure.

***We will rely on third parties for the foreseeable future for the manufacture of materials for our research programs, preclinical studies and clinical trials and we do not have long-term contracts with many of these parties. This reliance on third parties increases the risk that we will not have sufficient quantities of***



***such materials, product candidates, or any therapies 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.***

Although we plan on developing our own manufacturing facility, we expect to rely on third parties for the next several years for the manufacture of materials for our planned clinical trials and preclinical and clinical development. We expect to rely in part on third parties for commercial manufacture if any of our product candidates receive marketing approval. We do not have a long-term agreement with any of the third-party manufacturers we currently use to provide preclinical and clinical materials, and we purchase any required materials on a purchase order basis. Certain of these manufacturers are critical to our production and the loss of these manufacturers to one of our competitors or otherwise, or an inability to obtain quantities at an acceptable cost or quality, could delay, prevent, or impair our ability to timely conduct preclinical studies or clinical trials, and would materially and adversely affect our development and commercialization efforts.

We expect to continue to rely in part on third-party manufacturers for the foreseeable future for the commercial supply of any of our product candidates for which we obtain marketing approval, if any. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation or unauthorized disclosure of our intellectual property or other proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP or similar foreign regulations for manufacturing our product candidates. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain authorization for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or a comparable foreign regulatory authority does not authorize these facilities for the manufacture of our product candidates or if it withdraws any such authorization in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. 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 revocation, seizures, or recalls of product candidates or drugs, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

***We are planning to acquire and establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on CDMOs for the manufacture of our product candidates, which will be costly, time-consuming, and which may not be successful.***

We are looking to lease a facility to buildout a manufacturing facility as an alternative or in addition to our reliance on CDMOs for the manufacture of drug substance for preclinical and clinical needs. If the lease is entered into, we plan to renovate and customize the manufacturing facility for our use. We expect that construction of our own manufacturing facility will provide us with enhanced control of material supply for preclinical studies and clinical trials, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience as a company in construction of a manufacturing facility and may never be successful in building our own manufacturing facility or capability. As a result, we will also need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, manufacture and eventual commercialization, if approved, of our product candidates. We, as a company, have no experience in setting up, building, or eventually managing a manufacturing facility. If we failed to select the correct location, or if we fail to enter into the lease agreement, or fail to complete the planned renovation and customization in an efficient manner, or fail to recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the FDA and other foreign 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 or other foreign regulatory authorities may require that we not distribute a lot until the relevant 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 or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects. Problems in our manufacturing process could restrict our ability to meet clinical and market demand for our products.

We also may encounter problems hiring and retaining the experienced scientific, quality-control, and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities 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.

***We do not have experience as a company managing a manufacturing facility.***

Operating our own manufacturing facility will require significant resources, and we do not have experience as a company in managing a manufacturing facility. In part because of this lack of experience, we cannot be certain that our manufacturing plans will be completed on time, if at all, or if manufacturing of product candidates from our own manufacturing facility for our planned clinical trials will begin or be completed on time, if at all. In part because of our inexperience, we may have unacceptable or inconsistent product quality success rates and yields, and we may be unable to maintain adequate quality control, quality assurance, and qualified personnel. In addition, if we switch from our current CDMOs to our own manufacturing facility for one or more of our product candidates in the future, we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Failure to successfully obtain and operate our planned manufacturing facility could adversely affect the commercial viability of our product candidates.

***We or our third-party manufacturers may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which may impair the clinical advancement and commercialization of our product candidates.***

In order to conduct clinical trials of our product candidates and commercialize any approved product candidates, we and our manufacturing partners need to manufacture them in large quantities. However, we or they may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities, as discussed above. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of these product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting products may be delayed or not obtained, which could significantly harm our business. Supply sources could be interrupted from time to time and, if interrupted, it is not certain that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost, or at all. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

***We have a limited number of suppliers for the lipid excipients used in our product candidates and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our product candidates. If we obtain regulatory approval for any of our product candidates, we would need to expand the supply of lipid excipients in order to commercialize them.***

We have a limited number of suppliers for the lipid excipient component of our product candidates. We also do not have long-term supply agreements with all of our lipid suppliers. We may not be able to establish additional sources of supply for the lipid excipient component of our product candidates, or may be unable to do so on acceptable terms.

The number of suppliers of the lipid excipients for our product candidates is limited. In the event it is necessary or desirable to acquire lipid excipients from alternative suppliers, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company, and redesign of processes can trigger the need for conducting additional studies such as comparability or bridging studies. Additionally, certain of our suppliers are critical to our production, and the loss of these suppliers to one of our competitors or otherwise would materially and adversely affect our development and commercialization efforts.

***We rely, and expect to continue to rely, on third parties to conduct certain aspects of our preclinical studies and will rely on third parties to conduct our planned clinical trials. Any failure by a third party to conduct the planned clinical trials according to GCPs and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.***

We have relied upon and plan to continue to rely upon third parties to conduct certain aspects of our preclinical studies and will depend on third parties to conduct our planned clinical trials and to monitor and manage data for our ongoing preclinical and planned clinical programs. We rely on these parties for execution of our preclinical studies and will rely on these parties for execution of our planned clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations or similar foreign regulations outside of the United States. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Any third parties conducting our planned clinical trials or preclinical studies are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to

such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our planned clinical trials may be extended, delayed, or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities that could harm our competitive position. In addition, principal investigators for our planned clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash and cash equivalents or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any BLA we submit to the FDA, or any comparable foreign regulatory applications we submit to foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators, and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired preclinical and clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

***We may collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.***

We may seek collaborative relationships for the development and commercialization of our product candidates. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate product revenue from these arrangements with commercial entities 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 product candidates pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information inappropriately or in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property rights covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

- collaborators may decide not to 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 collaborators' 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, 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 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 product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished, or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, devices, materials, know-how, or intellectual property of the collaborator relating to our product candidates;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short- and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- 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; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations from other companies with substantially greater financial, marketing, sales, technology, or other business resources. Business combinations among biotechnology and pharmaceutical companies have also resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and 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 or 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.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also 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. Any collaborator may also be subject to many of the risks relating to product development, regulatory

approval, and commercialization described in this “Risk Factors” section, and any negative impact on our collaborators may adversely affect us.

***Our employees and independent contractors, including principal investigators, CDMOs, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.***

Misconduct by our employees and independent contractors, including principal investigators, CDMOs, CROs, consultants, vendors, and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance, and other pharmaceutical functions and commercialization, could include intentional, reckless, or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities as well as similar healthcare laws and regulations in foreign jurisdictions, including those laws that require the reporting of true, complete, and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud, and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete, and accurate financial information and data. Specifically, 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 may restrict or prohibit a wide range of pricing, discounting, marketing, and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of preclinical studies or clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight, and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

***If our CDMOs use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our manufacturers. Our manufacturers are subject to federal, state, and local laws and regulations in the United States and in the countries in which they operate governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Generally, we do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition or results of operations.

### **Risks Related to Intellectual Property**

***If we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual***

***property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property and prevent others from duplicating our pipeline product candidates, or their use or manufacture, or any of and any future product candidates, and 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 such product candidates.

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. Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, CROs, consultants, scientific advisors, and other contractors, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and some remain so until issued. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file any patent application related to an invention or product candidate. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal, factual, and scientific questions and can be uncertain. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge the inventorship, ownership, validity, enforceability, or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Additionally, any U.S. provisional patent application that we file is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent application, we may lose our priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. In addition, no assurances can be given that third parties will not create similar or alternative products or methods that achieve similar results without infringing upon our patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold with respect to our programs or product candidates fail to issue, if the breadth or strength of protection of our current or future issued patents is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, or threaten our ability to commercialize our current or future product candidates. Several patent applications covering our product candidates have been filed recently by us. We cannot offer any assurances about which, if any, will result in issued patents, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our patents may be challenged in courts or patent offices in the United States and abroad. In

addition, the issuance of a patent does not give us the right to practice the patented invention, as third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology.

Wide-ranging patent reform legislation in the United States, including the Leahy-Smith America Invents Act of 2011, or the Leahy-Smith Act, may increase the uncertainty of the strength or enforceability of our intellectual property and the cost to defend it. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. Under the Leahy-Smith Act, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be prompt going forward during the time from invention to filing of a patent application and to be diligent in filing patent applications, but circumstances could prevent us from promptly filing or prosecuting patent applications on our inventions. The Leahy-Smith Act also enlarged the scope of disclosures that qualify as prior art. Furthermore, if a third party filed a patent application before effectiveness of applicable provisions of the Leahy-Smith Act, on March 16, 2013, an interference proceeding in the United States can be initiated by a third party to determine if it was the first to invent any of the subject matter covered by the claims of our patent applications. We may also be subject to a third party preissuance submission of prior art to the USPTO.

The Leahy-Smith Act created for the first time new procedures to challenge issued patents in the United States, including post-grant review, *inter partes* review and derivation proceedings, which are adversarial proceedings conducted at the USPTO, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, which all of our patent filings have, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas *inter partes* review proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the USPTO include review of patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts. The USPTO issued a final rule effective November 13, 2018 announcing that it will now use the same claim construction standard currently used in the U.S. federal courts to interpret patent claims in USPTO proceedings, which is the plain and ordinary meaning of words used. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us, including 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 a result of all of the foregoing, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Third-party claims of intellectual property infringement, misappropriation or other violation may result in substantial costs or prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on our avoiding actual and allegations of infringement, misappropriation or other violation of the patents and other proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, re-examination, and post-grant and *inter partes* review proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the European Patent Office, or EPO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Many companies in intellectual property-dependent industries, including the pharmaceutical industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. As biotechnology and pharmaceutical industries expand and more patents



are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to composition of matter, drug delivery, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We cannot guarantee that our technologies, products, compositions, and their uses do not or will not infringe, misappropriate or otherwise violate third-party patent or other intellectual property rights. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any third-party patents were held by a court of competent jurisdiction to cover the composition of matter of any of our product candidates, the manufacturing process of any of our product candidates or the method of use for any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, which may not be available at all or on commercially reasonable terms, or until such patents expire.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of the merit of such claims. We may not be aware of all intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe, misappropriate, or otherwise violate such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate, or otherwise violate any third party's intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates and/or harm our reputation and financial results. Defense of these claims, regardless of their merit, could involve substantial litigation expense and could be a substantial diversion of management and employee resources from our business. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, in the case of claims concerning registered trademarks, rename our product candidates, or obtain one or more licenses from third parties, which may require substantial time and monetary expenditure, and which might be impossible or technically infeasible. Furthermore, 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; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For patents that are eligible for extension of patent term, we expect to seek extensions of patent terms in the United States and, if available, in other countries, however there can be no assurance that we will be granted any patent term extension we seek, or that any such patent term extension will provide us with any competitive advantage.

***If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be harmed.***

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates, 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 Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the EU, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

***We depend on proprietary technology licensed from others. If we lose our existing licenses, we may not be able to continue developing our product candidates.***

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others.

We depend substantially on our agreements with Flagship Pioneering Innovations V, Inc., or Flagship, the Whitehead Institute for Biomedical Research, or WIBR, and Acuitas Therapeutics, Inc., or Acuitas, including the licenses granted thereunder. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

We may also enter into additional agreements, including license agreements, with other parties in the future that impose diligence, development and commercialization timelines, milestone payments, royalties, insurance, and other obligations on us. We are also obligated to achieve certain development milestones with respect to licensed products in our fields of use within specified time periods. If we fail to comply with our obligations to Flagship, WIBR, Acuitas, or any of our other current or future licensors or collaborators, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture, or market any product candidate that is covered by these agreements, which could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We rely on Flagship, WIBR, and Acuitas to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over their activities or their use or licensing of any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

***If we are unable to obtain licenses from third parties on commercially reasonable terms or at all, or fail to comply with our obligations under such agreements, our business could be harmed.***

It is necessary for us to use the patented or other proprietary technology of third parties to commercialize our products. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license in the future, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning or otherwise controlling such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, 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 technology and product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Additionally, if we fail to comply with our obligations under any future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing, or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

***Although we are not currently involved in any relevant litigation, we may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.***

Competitors and other third parties may infringe, misappropriate, or otherwise violate our or our future licensors' patents, trademarks, copyrights, or other intellectual property. As a result, we may need to file infringement, misappropriation, or other intellectual property-related claims against third parties. To counter infringement or other unauthorized use, we may be required to file claims on a country-by-country basis, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which often last for years before they are concluded.

Our license agreements have certain limitation on our ability to enforce the licensed patents against third party infringers. For example, with regard to our license agreements with WIBR, we cannot enforce the licensed patents against a certain third party, who previously entered into a sponsored research agreement with WIBR,

with respect to inventions arising out of such sponsored research agreement. In addition, with respect to the WIBR Co-Exclusive Agreement, the WIBR patent rights are co-exclusively licensed to both us and one other third party. As such, we are not permitted to assert the co-exclusively licensed patent rights against the co-exclusive licensee.

Any claims we assert against third parties could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we have asserted are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

In any such proceeding, a court may decide that a patent of ours, or a patent that we in-license, is not valid, is unenforceable and/or is not infringed, or may construe such patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or held unenforceable in whole or in part, could put our patent applications at risk of not issuing, and could limit our ability to assert those patents against those parties or other competitors and curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace.

Even if we establish infringement, misappropriation, or other violation of our intellectual property, the court may decide not to grant an injunction against further such activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Weakening patent laws and enforcement by courts and other authorities in the United States and other jurisdictions may impact our ability to protect our patents.***

The U.S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making and other bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce and defend our existing patents and patents that we might obtain in the future.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be

substantially harmed. For example, we could become a party to foreign opposition proceedings, such as at the EPO, or patent litigation and other proceedings in a foreign court. If so, uncertainties resulting from the initiation and continuation of such proceedings could have a material adverse effect on our ability to compete in the marketplace. The cost of foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party.

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

The USPTO, EPO and other patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay such fees due to non-U.S. patent agencies. While, in many 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 in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors or other third parties 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.

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

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but where enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity, or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy, and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, or other forms of intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to

result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions including EU countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some 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 are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

***We rely on our ability to stop others from competing by enforcing our patents, however some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.***

Many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, in certain circumstances. For example, compulsory licensing, or the threat of compulsory licensing, of life-saving products and expensive products is becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Compulsory licenses could be extended to include some of our product candidates, if they receive marketing approval, which may limit our potential revenue opportunities. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products where such patent rights exist, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement if a government is the infringer, which could materially diminish the value of the patent.

***Some of our intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights and our ability to contract with non-U.S. manufacturers.***

The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant

or applicants" if it determines that (1) adequate steps have not been taken to commercialize the invention and achieve practical application of the government-funded technology, (2) government action is necessary to meet public health or safety needs, (3) government action is necessary to meet requirements for public use under federal regulations or (4) we fail to meet requirements of federal regulations. If the patent owner refuses to do so, the government may grant the license itself. Some of our licensed patents are subject to the provisions of the Bayh-Dole Act. If our licensors fail to comply with the regulations of the Bayh-Dole Act, they could lose title to any patents subject to such regulations, which could affect our license rights under the patents and our ability to stop others from using or commercializing similar or identical technology and products, or limit patent protection for our technology and products.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is either not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, CROs, consultants, scientific advisors, and other contractors. 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. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements, or security measures may be breached and our trade secrets could be disclosed, and we may not have adequate remedies for any such breach. 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. Misappropriation or unauthorized disclosure of our trade secrets or other confidential proprietary information could cause us to lose trade secret protection, impair our competitive position and have a material adverse effect on our business. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Additionally, if the steps taken to maintain our trade secrets or other confidential proprietary information are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret or other confidential proprietary information.

Further, we cannot provide any assurances that competitors or other third parties will not otherwise gain access to our trade secrets and other confidential proprietary information or independently discover or develop substantially equivalent technology and processes. If we are unable to prevent disclosure of the trade secrets and other non-patented intellectual property related to our product candidates and technologies to third parties, there is no guarantee that we will have any such enforceable trade secret protection and we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations, and financial condition.

***We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties, that our employees have wrongfully used or disclosed alleged trade secrets of their former employers, or asserting ownership of what we regard as our own intellectual property.***

We have employed, and may in the future employ, individuals who 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 independent contractors 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 our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of such individuals' former employers or other third parties. 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, or

our ability to hire personnel, which, in any case of the foregoing, could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Although it is our policy to require all of our employees and consultants to assign their inventions to us, to the extent that employees or consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We may also 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 of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Our proprietary rights may not adequately protect our technologies and product candidates, and intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

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

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of our patents;
- others, including inventors or developers of our patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing, misappropriating, or otherwise violating our intellectual property rights;
- we might not have been the first to conceive and reduce to practice the inventions covered by our patents or patent applications;
- we might not have been the first to file patent applications covering certain of our inventions;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- our pending patent applications might not result in issued patents;
- there might be prior public disclosures that could invalidate our patents;
- our issued patents may not provide us with any commercially viable products or competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity, or enforceability of our patents or patent applications may be challenged by third parties; and
- the patents or pending or future applications of third parties, if issued, may have an adverse effect on our business.



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

### **Risks Related to Employee Matters, Managing Growth, and Other Risks Related to Our Business**

***We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

We expect to experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory and clinical affairs, medical affairs, legal and finance, and sales, marketing and distribution. To manage our growth activities, we must continue to implement and improve our managerial, operational, and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. As we expand our organization, we may have difficulty identifying, hiring, and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including:

- the need to identify, recruit, maintain, motivate, and integrate additional employees, consultants, and contractors;
- managing our internal development efforts effectively, including clinical development and regulatory review for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow product revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to develop and commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services, including preclinical development activities and manufacturing. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our planned clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited.

***If we lose our executive officers, are unable to recruit qualified officers or other key personnel, our business may materially suffer.***

We are highly dependent on our management, including our Chief Executive Officer, Mahesh Karande, our Chief Scientific Officer, Thomas McCauley, our Chief Financial Officer, Roger Sawhney, and our Chief Medical Officer, Yan Moore. Due to the specialized knowledge each of our executive officers possesses with respect to our product candidates and our operations, the loss of service of any of our executive officers could delay development of our product candidates or adversely impact our business operations. We do not carry key person life insurance on any of our executive officers. In general, the employment arrangements that we have with our executive officers do not prevent them from terminating their employment with us at any time.

In addition, our future success and growth will depend in part on the continued service of our employees and management personnel and our ability to identify, hire, and retain additional personnel. Replacing key employees and management personnel may be difficult or costly and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or effectively incentivize key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for 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 engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

***We may engage in acquisitions or strategic collaborations that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause us to incur debt or assume contingent liabilities, and subject us to other risks.***

In the future, we may enter into transactions to acquire other businesses, products, or technologies or enter into strategic collaborations, including licensing. If we do identify suitable acquisition or collaboration, we may not be able to complete such acquisitions or collaboration on favorable terms, or at all. Any acquisitions or collaboration we enter into may not strengthen our competitive position, and we may never realize the anticipated benefits of such acquisitions or collaborations. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business or collaboration that are not covered by the indemnification we may obtain from the seller or our collaborator. In addition, we may not be able to successfully integrate any acquired personnel, technologies, and operations into our existing business in an effective, timely, and non-disruptive manner. Acquisitions or collaborations may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash and cash equivalents available for operations and other uses. We cannot predict the number, timing, or size of future acquisitions or collaborations or the effect that any such transactions might have on our operating results.

***The COVID-19 pandemic has impacted, and will likely continue to impact, our operations and may materially and adversely affect our business and financial results in the future.***

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, surfaced in Wuhan, China. Since then, COVID-19 has spread globally. We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. To provide a safe work environment for our employees, we have implemented various measures to promote for social distancing, increase sanitization of our facilities and provide personal protective equipment for our employees. The COVID-19 pandemic continues to evolve, and we cannot predict how new executive orders

or other preventative measures, if any, could impact our ability to conduct our business and our product candidate development programs. Any severe disruptions in our operations as a result could negatively impact our business, results of operations, and financial condition.

In addition, quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 (and its variants) or other infectious diseases have impacted and may continue to impact our third-party service providers.

Our development efforts may be further affected by the COVID-19 pandemic, including:

- interruptions in preclinical studies due to restricted or limited operations at our or our third-party service providers' laboratory facilities, including the collection and analysis of data, or unavailability of materials;
- delays in receiving approval from regulatory authorities to initiate clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling patients, including patients who may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- delays in clinical sites receiving the supplies and materials needed to conduct clinical trials;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state, or provincial governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- limitations in employee resources that would otherwise be focused on the conduct of clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption in global shipping that may affect the transport of clinical trial materials or make such transport significantly more expensive;
- changes in local regulations, guidance, or practice as part of a response to the COVID-19 pandemic, which may require changes in the ways in which clinical trials are conducted or to discontinuation of clinical trials;
- delays in necessary interactions with regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA or other comparable foreign regulatory authorities to accept data from clinical trials in geographies affected by COVID-19.

The extent to which the COVID-19 pandemic may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the effectiveness and timing of vaccines, the effectiveness of actions taken in the United States and other countries to contain and treat the disease, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, reopening plans, and the resurgence of COVID-19 or the emergence of new strains of COVID-19. The impact to our operations due to the COVID-19 pandemic could be severe and could negatively affect our business, financial condition, and results of operations. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risk factors described in this "Risk Factors" section.

***Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.***

We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by third parties in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients, or stockholders.

Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may seriously harm our business, overall financial condition, and results of operations. Insurance may not cover existing or future claims, be sufficient to fully compensate us for one or more of such claims, or continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby adversely impacting our results of operations.

**Risks Related to Our Common Stock**

***The market price of our common stock may be volatile and fluctuate substantially.***

Our stock price is likely to be volatile. As a result of this volatility, you may not be able to sell your common stock at a profit. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of our ongoing, planned, or any future preclinical studies, clinical trials, or clinical development of our product candidates or those of our competitors;
- unanticipated serious safety concerns related to the use of our product candidates;
- developments related to any future collaborations;
- developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- regulatory or legal developments in the United States and other countries;
- development of third-party product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less attractive;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate a clinical trial;
- our failure to commercialize our product candidates;
- announcements by us, our collaborators or our competitors of significant acquisitions, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents, or other intellectual property or proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

- changes in accounting practices;
- the trading volume of our common stock;
- our cash and cash equivalents position;
- our ability to effectively manage our growth;
- sales of our common stock by us or our stockholders in the future;
- expiration of market stand-off or lock-up agreements;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- significant lawsuits, including intellectual property or stockholder litigation;
- the results of our efforts to engineer, develop, acquire, or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, the stock market in general, and the Nasdaq Global Select Market, or Nasdaq, and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, and results of operations.

***Our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to control all matters submitted to stockholders for approval.***

Based on the number of shares of common stock outstanding as of March 4, 2022, our executive officers, directors, and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 71% of our outstanding voting stock. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders would control the election of directors, the composition of our management and approval of any merger, consolidation, or sale of all or substantially all of our assets. This may prevent a change in our management or discourage unsolicited acquisition proposals or offers for our shares of common stock that you may feel are in your best interest as one of our stockholders.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of an aggregate of 34,678,733 shares of our common stock have rights,

subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the stockholders' agreement between us and such holders. We also have registered all shares of common stock that we may issue under our equity compensation plans and these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the closing of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common shares that are held by non-affiliates to exceed \$700 million as of the last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this Annual Report;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this Annual Report. In particular, in this Annual Report, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. Further, even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced obligations regarding executive compensation in our periodic reports and proxy statements. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

***We are a “smaller reporting company” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.***

We are considered a “smaller reporting company.” We are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as an exemption from providing selected financial data and executive compensation information. If we qualify as a smaller reporting company because we meet the revenue limits under the definition of a smaller reporting company, we will be a “low-revenue smaller reporting company.” Low-revenue smaller reporting companies are not required to obtain an external audit on the effectiveness of their internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404. These exemptions and reduced disclosures may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

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

As a public company, and particularly after we are no longer an emerging growth company, we continue to incur significant legal, accounting and other expenses that we did not incur before we became a public 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. Our management and other personnel are devoting a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, in our second annual report due to be filed with the SEC after becoming a public company, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company or a low-revenue smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We may discover significant deficiencies or material weaknesses in our internal control over financial reporting, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our consolidated financial statements. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

***If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.***

We are not currently required to comply with the rules of the SEC implementing Section 404 and, therefore, we are not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act of 2002, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Although we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. As an emerging growth company and a low-revenue smaller reporting company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an emerging growth company or a low-revenue

smaller reporting company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

To comply with the requirements of being a public company, we have undertaken and will need to undertake additional actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. In addition, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline, even if our business is doing well.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have limited research coverage by securities and industry analysts. If any of the analysts who cover us downgrades our common stock or issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***Provisions in our amended and restated certificate of incorporation and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it



more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend, or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president, or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

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

***Our amended and restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.***

Our amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders, other than suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction and any action that the Court of Chancery of the State of Delaware has dismissed for lack of subject matter jurisdiction, which may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also specifies that unless we consent in writing to the selection of an alternate forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, or the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes or federal judges experienced in resolving Securities Act disputes, efficient administration of cases on a more expedited schedule relative to other forums

and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees, and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees, or agents and result in increased costs for stockholders to bring a claim. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

***Our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income may be subject to certain limitations.***

As of December 31, 2021, we had U.S. federal and state net operating loss carryforwards, or NOLs, of \$125.8 million and \$123.0 million, respectively, which may be available to offset future taxable income, if any. As of December 31, 2021, we also had federal and state research and development credit carryforwards of \$3.4 million and \$2.8 million, respectively. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change by value in its equity ownership over a rolling three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Sections 382 and 383 of the Code. For these reasons, we may not be able to utilize a material portion of the NOLs or research and development credit carryforwards even if we attain profitability.

### **General Risks**

***Our business and operations may suffer in the event of system failures, deficiencies, or intrusions which could materially affect our results.***

Our information technology systems, as well as those of our CROs and other contractors and consultants, are vulnerable to failure or damage from computer viruses and other malware (e.g., ransomware), unauthorized access or other cybersecurity attacks, natural disasters (including hurricanes), terrorism, war, fire, and telecommunication or electrical failures. In the ordinary course of our business, we directly or indirectly collect, store, and transmit sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data, and health-related information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third parties. The secure processing, maintenance, and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to human error (e.g., social engineering, phishing), a technical vulnerability, malfeasance, or other disruptions. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, or breaches in our systems or those of our CDMOs, CROs and other contractors and consultants.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or our critical third parties' operations, it could result in a material disruption of our product candidate development programs, our operations and ultimately, our financial results. For example, the loss of preclinical studies or clinical trial data from completed, ongoing, or planned studies or trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential, or proprietary information, we could incur liability and the further development of our product candidates could be delayed. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, or stolen.

Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

***We or the third parties upon whom we depend may be adversely affected by natural disasters or pandemics and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural disasters or pandemics, other than or in addition to COVID-19, could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, pandemic, such as the COVID-19 pandemic, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.***

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. For example, the COVID-19 pandemic has resulted in widespread unemployment, an economic slowdown and extreme volatility in the capital markets. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers, CDMOs, or other third-party providers may not survive an economic downturn. As a result, our business, results of operations and price of our common stock may be adversely affected.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.***

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all available funds and future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

## Item 1B. Unresolved Staff Comments.

Not Applicable.

## Item 2. Properties.

We occupy office and laboratory space in Cambridge, Massachusetts under a shared space arrangement that expires in July 2023. We have entered into a lease agreement with ARE-MA Region No. 94, LLC for office and laboratory space in Cambridge, Massachusetts, which is currently being built out. We currently anticipate commencing this lease at the earliest in late 2022 upon completion of construction. Upon completion of construction and our commencement of our occupancy within the space, the lease will expire in 2037, subject to certain extension rights. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

## Item 3. Legal Proceedings.

We are not subject to any material legal proceedings.

## Item 4. Mine Safety Disclosures.

Not applicable.

## INFORMATION ABOUT OUR EXECUTIVE OFFICERS AND DIRECTORS

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this Annual Report on Form 10-K:

Name	Age	Position
<b>Executive Officers</b>		
Mahesh Karande	49	President, Chief Executive Officer and Director
Roger Sawhney, M.D.	52	Chief Financial Officer
Thomas McCauley, Ph.D.	53	Chief Scientific Officer
Yan Moore, M.D.	55	Chief Medical Officer
<b>Non-Employee Directors</b>		
Noubar B. Afeyan, Ph.D.	59	Chairman of the Board of Directors
David A. Berry, M.D., Ph.D.	44	Director
Luke M. Beshar	63	Director
Elliott M. Levy, M.D.	63	Director
John Mendlein, Ph.D., J.D.	62	Director
Mary T. Szela	58	Director
Richard A. Young, Ph.D.	67	Director

### Executive Officers

**Mahesh Karande** has served as the President and Chief Executive Officer and as a member of our board of directors since June 2019. From April 2018 to March 2019, Mr. Karande served as President and CEO of Macrolide Pharmaceuticals (subsequently Zikani Pharmaceuticals). From March 2010 to April 2017, Mr. Karande held senior leadership roles at Novartis, including VP and Franchise Head, US Oncology, President Novartis Africa and President Novartis Egypt. Mr. Karande holds an M.B.A. from the Wharton School, University of Pennsylvania. He is also a graduate of the Georgia Institute of Technology where he completed his M.S. in engineering and the University of Bombay where he completed his undergraduate studies in engineering. We believe that Mr. Karande's extensive life science and leadership experience qualifies him to serve on our board of directors.

**Roger Sawhney, M.D.**, has served as the Chief Financial Officer of our company since May 2020. From September 2018 to February 2020, Dr. Sawhney served at KKR & Co., a global investment firm, as Director of its healthcare investment platform in the Americas where his work focused on investments across private and growth equity in the healthcare sector. From August 2009 to August 2012, Dr. Sawhney served as Senior Vice President and Head of Global Corporate Strategy for Novartis AG, as well as Senior Vice President of Corporate Strategy and Business Development for Outcome Health from February 2017 to February 2018. Dr. Sawhney has also served as Partner with Bain & Company from August 2012 to February 2017 and the Boston Consulting Group where he managed numerous client engagements across the life sciences, med-tech and digital health sectors. Dr. Sawhney holds an M.D. from Harvard Medical School and a BA in Economics from Stanford University.

**Thomas McCauley, Ph.D.**, has served as the Chief Scientific Officer of our company since July 2019. From September 2018 to July 2019, Dr. McCauley served as Chief Scientific Officer of Macrolide Pharmaceuticals (subsequently Zikani Therapeutics) and as Chief Scientific Officer of Translate Bio (formerly RaNA Therapeutics) from September 2016 to April 2018. From April 2010 to August 2016, Dr. McCauley served as vice president and head of Global Nonclinical Development at Shire Pharmaceuticals, where he contributed to the development and global approvals of many of Shire's products, including Replagal® for Fabry disease, Vpriv® for Gaucher disease, Elaprase® for Hunter syndrome, Firazyr® for hereditary angioedema and Xiidra® for dry eye disease. Dr. McCauley holds a Ph.D. from the University of Alabama at Birmingham and a B.S. and M.Eng. from Cornell University.

**Yan Moore, M.D.**, has served as the Chief Medical Officer of our company since January 2022. From September 2018 to December 2021, Dr. Moore served as Senior Vice President, Head of Oncology Therapeutic Area at Ipsen Pharmaceuticals. From September 2016 to September 2018, Dr. Moore was the Chief Medical Officer and Senior Vice President of Clinical Development and Research and Development at Anchiano Therapeutics (previously BioCanCell Therapeutics). Earlier in his career, Dr. Moore held various roles of increasing responsibility spanning global medical affairs and clinical development at Ariad, Sanofi, GlaxoSmithKline and Bristol Myers-Squibb. As a clinician, Dr. Moore spent time at Sapir Medical Center, Meir Hospital and Edith Wolfson Medical Center. Dr. Moore received his Medical degree and Bachelor of Medical Sciences from the Sackler School of Medicine at Tel Aviv University, Master of Business Administration from the LeBow College of Business at Drexel University, and completed the Advanced Management Program at Harvard Business School.

#### **Non-Employee Directors**

**Noubar B. Afeyan, Ph.D.**, is a co-founder and has served as Chairman of our board of directors since 2016. In 1999, Dr. Afeyan founded Flagship Pioneering and serves as its Senior Managing Partner and Chief Executive Officer. Since 2010, Dr. Afeyan has served as Chairman of Moderna, Inc. and since 2013 has served on the board of directors of Rubius Therapeutics, Inc., both publicly traded companies. He has previously served on the boards of numerous privately and publicly held companies, including Evelo Biosciences, Inc., Kaleido Biosciences, Inc. and Seres Therapeutics, Inc. He received a Ph.D. in biochemical engineering from the Massachusetts Institute of Technology and a B.S. in chemical engineering from McGill University. Dr. Afeyan was previously a visiting lecturer of business administration at Harvard Business School and was previously a senior lecturer at MIT's Sloan School of Management where he taught courses on technology-entrepreneurship, innovation and leadership. We believe that Dr. Afeyan's significant experience co-founding, leading, and investing in numerous biotechnology companies make him qualified to serve on our board of directors.

**David A. Berry, M.D., Ph.D.**, has served as a member of our board of directors since August 2017. Dr. Berry has also served in roles of increasing responsibility at Flagship Pioneering Inc. since January 2005, most recently as General Partner. He previously served as a director of Axcella Health, Inc. and Evelo Biosciences, Inc. He holds an M.D. from Harvard Medical School, a Ph.D. in biological engineering from the Massachusetts Institute of Technology Biological Engineering Division and a B.S. in brain and cognitive sciences from the Massachusetts Institute of Technology. We believe that Dr. Berry's extensive experience in the life sciences industry qualifies him to serve on our board of directors.

**Luke M. Beshar** has served as a member of our board of directors since May 2021. Mr. Beshar has over 30 years of experience in executive leadership and chief financial officer roles principally for publicly traded and privately held pharmaceutical companies. Mr. Beshar has served as chairperson of the board of directors since January 2020 and as a member of the board of directors since October 2018 of Protara Therapeutics, a publicly

traded immuno-oncology company. Mr. Beshar served on the board of directors of Trillium Therapeutics Inc., a publicly traded clinical stage immuno-oncology company from March 2014 until November 2021 when the company was acquired by Pfizer. Mr. Beshar served on the board of directors of REGENXBIO, Inc., a publicly traded leading clinical-stage gene therapy company, from May 2015 until September 2021. Previously, Mr. Beshar served as executive vice president, chief financial officer of NPS Pharmaceuticals, Inc., a publicly traded global biopharmaceutical company focused on rare diseases, from 2007 until February 2015 when the company was acquired by Shire plc. Prior to NPS Pharmaceuticals, Mr. Beshar served as executive vice president, chief financial officer of Cambrex Corporation, a publicly traded manufacturer of branded and generic active pharmaceutical ingredients and provider of related services from 2002 until 2007. Mr. Beshar began his career with Arthur Andersen & Co. and is a certified public accountant. Mr. Beshar earned his B.A. in accounting and financial administration from Michigan State University and is a graduate of The Executive Program at the Darden Graduate School of Business at the University of Virginia. We believe that Mr. Beshar's extensive leadership experience in the pharmaceutical industry qualifies him to serve on our board of directors.

**Elliott M. Levy, M.D.**, has served on our board of directors since March 2021. Dr. Levy has served as Senior Vice President of Global Development of Amgen since September 2014 and Senior Vice President of R&D Strategy and Operations since June 2020. He served as Chairman of the board of TransCelerate BioPharma, Inc., a privately held company, from September 2017 to September 2019 and as a board member from May 2015 to May 2021, and has also served on the board of directors of NuCana plc since November 2021. Dr. Levy received his M.D. from Yale University and his B.A. from Yale College. We believe Dr. Levy is qualified to serve on our board of directors because of his scientific expertise and experience in the industry.

**John Mendlein, Ph.D., J.D.**, has served as a member of our board of directors since January 2020. Dr. Mendlein currently serves as an Executive Partner at Flagship Pioneering. From January 2018 to February 2019, Dr. Mendlein served as President of Corporate and Product Strategy of Moderna, Inc. From 1996 until 2017, Dr. Mendlein held different senior executive and board roles, including Executive Chairman, Chief Executive Officer and General Counsel, of various biotechnology companies, including Affinium Pharmaceuticals (acquired by Debiopharm Group), Adnexus Therapeutics (acquired by BMS), aTyr Pharma, Inc., or aTyr, Aurora Biosciences (acquired by Vertex), and Fate Therapeutics, Inc., or Fate. From 2011 to 2017, he also served as Chief Executive Officer of aTyr. He started his biotechnology career at Smith Kline and French (now GlaxoSmithKline). He currently serves as Vice Chairman of the board of directors of Fate and previously served on the public boards of directors of Moderna, Monogram, aTyr, and Editas Medicine, Inc. Dr. Mendlein holds a Ph.D. in physiology and biophysics from the University of California, Los Angeles, a J.D. from the University of California, Hastings College of the Law, and a B.S. in biology from the University of Miami. We believe that Dr. Mendlein's extensive scientific experience and experience in the biotechnology industry qualifies him to serve on our board of directors.

**Mary T. Szela** has served as a member of our board of directors since June 2019. Ms. Szela currently serves as the Chief Executive Officer and President of TriSalus Life Sciences, Inc. (formerly Surefire Medical, Inc.), a privately held immuno-oncology company. From January 2016 to November 2016, Ms. Szela served as Chief Executive Officer and a director of Aegerion Pharmaceuticals, Inc. In November 2016, Aegerion Pharmaceuticals, Inc. merged with QLT Inc. to form Novelion Therapeutics Inc. where Ms. Szela served as Chief Executive Officer and as a member of its board of directors until November 2017. Ms. Szela served as the Chief Executive Officer and a member of the board of directors of Melinta Therapeutics, Inc., an antibiotic development company, from April 2013 to August 2015. Ms. Szela held ascending management positions at Abbott Laboratories from 1987 to 2012, including President of the company's U.S. pharmaceutical business from January 2008 to December 2010. Ms. Szela has served as a member of the public boards of directors of Kura Oncology, Inc. since November 2018, Prometheus Biosciences since March 2021, Coherus Biosciences from 2014 to August 2021 and Alimera Sciences Inc. from June 2018 to March 2021. Ms. Szela has also served as a member of the board of directors of TriSalus Life Sciences, Inc., a privately held company, since January 2018. She also previously served as a member of the board of directors of Receptos, Inc. from June 2014 to July 2015, Novo Nordisk from March 2014 to March 2017, and Macrolide Pharmaceuticals, from March 2018 to July 2019. Ms. Szela earned an M.B.A. in Business and a B.S. in nursing, both from the University of Illinois. We believe that Ms. Szela's extensive leadership experience in the pharmaceutical industry qualifies her to serve on our board of directors.

**Richard A. Young, Ph.D.**, has served on our board of directors since August 2017. He has been a member of the Whitehead Institute and Professor of Biology at the Massachusetts Institute of Technology since 1984. Dr. Young currently serves as a member of the boards of directors of Syros Pharmaceuticals, Inc. since

November 2011, Camp4 Therapeutics, Inc. since February 2016, and Dewpoint Therapeutics, Inc. since October 2020. In May 2012, he was elected into the National Academy of Sciences and in October of 2019, he was elected to the National Academy of Medicine. Dr. Young received his Ph.D. in molecular biophysics and biochemistry from Yale University. We believe Dr. Young is qualified to serve on our board of directors because of his scientific expertise.



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

***Market information***

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol "OMGA" since July 30, 2021. Prior to that time, there was no public market for our common stock.

***Holder***

As of March 4, 2022, there were approximately 62 holders of record of our common stock. The actual number of stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

***Dividend Policy***

We have never declared or paid any cash dividends on our common stock since our inception. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

***Recent sales of unregistered securities***

All unregistered securities sold by us during the year ended December 31, 2021 were previously disclosed in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

***Use of proceeds from registered securities***

On August 3, 2021, we completed our initial public offering ("IPO"). The offer and sale of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-257794), which was declared effective on July 29, 2021 (the "Registration Statement").

The net proceeds of approximately \$128.1 million from our IPO have been invested in interest-bearing savings account. Information related to our intended use of the proceeds from our IPO is included in the "Use of Proceeds" section of our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on August 2, 2021, and there has been no material change in our planned use of the balance of the net proceeds from our IPO described in such prospectus.

**Item 6. [Reserved]**

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing at the end of 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, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis. Please also see the "Special Note Regarding Forward-Looking Statements" section of this Annual Report on Form 10-K.*

### Overview

Omega Therapeutics is pioneering a systematic approach to use mRNA therapeutics as programmable epigenetic medicines by leveraging our OMEGA Epigenomic Programming platform ("OMEGA platform"). mRNA refers to Messenger RNA, a single-stranded RNA (ribonucleic acid that carries instructions for the synthesis of proteins) corresponding to the sequence of a gene. Our OMEGA platform harnesses the power of epigenetics, the mechanism that controls gene expression and every aspect of an organism's life from cell genesis, growth and differentiation to cell death. We have deciphered the three-dimensional architecture of the human genome. Genes and their accompanying regulators are organized into distinct and evolutionarily conserved structures called Insulated Genomic Domains, or IGDs. IGDs are the fundamental structural and functional units of gene control and cell differentiation and act as the "control room" of biology. Most diseases are caused by aberrant gene expression rooted in alterations in IGDs. The OMEGA platform has enabled us to systematically identify and validate thousands of novel DNA-sequence-based epigenomic "zip codes" associated with individual regulatory elements within IGDs. We call these epigenomic targets EpiZips. We rationally design and engineer our mRNA therapeutics, which are programmable and modular epigenetic medicines, called Omega Epigenomic Controllers, or OECs, to target EpiZips for Precision Genomic Control. This enables us to precisely tune genes to a desired level of expression and to control the duration of expression. Through this approach, we believe that the OMEGA platform has broad potential applicability across a range of diseases and conditions. Our pipeline currently consists of early-stage, preclinical programs that span oncology, multigenic diseases including immunology, regenerative medicine, and select monogenic diseases. We have conducted *in vivo* preclinical studies of our OECs in multiple disease models for various indications, including hepatocellular carcinoma, or HCC, non-small cell lung cancer, or NSCLC, and acute respiratory distress syndrome, or ARDS, and we expect to conduct *in vivo* preclinical studies for multiple additional programs. We initiated investigational new drug application ("IND") enabling studies for multiple programs in 2021, and we are aiming to submit an IND for our OEC candidate for the treatment of HCC and declare two OEC development candidates in the first half of 2022. We are also planning to submit an IND for another OEC candidate in the second half of 2022 or early 2023.

Since our inception, we have incurred significant operating losses. We have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our preclinical development activities and preparing for clinical trials of our product candidates. To date, we have funded our operations primarily with proceeds from sales of equity securities and borrowings under our loan and security agreement.

As of December 31, 2021 we had cash, cash equivalents and marketable securities of \$225.3 million. In August 2021, we completed our initial public offering ("IPO") pursuant to which we issued and sold 8,300,976 shares of our common stock, including 900,976 shares pursuant to the partial exercise of the underwriters' option to purchase additional shares, at a public offering price of \$17.00 per share, for aggregate gross proceeds of \$141.1 million. We received approximately \$128.1 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us.

Our ability to generate product revenue will depend on the successful development, regulatory approval, and eventual commercialization of one or more of our product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources. Additional sources of financing might not be available to us on favorable terms, if at all. If we are unable to raise additional funds through equity or debt financings when needed, we may be

required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We expect to continue to incur significant additional operating losses for the foreseeable future as we seek to advance product candidates through clinical development, continue preclinical development, expand our research and development activities, develop new product candidates, complete preclinical studies and clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. Our expenses will also increase substantially if or as we:

- continue our research and development efforts and submit INDs for our product candidates;
- initiate and conduct clinical trials of our product candidates;
- continue to engineer and develop additional product candidates;
- continue to develop the OMEGA platform;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical trials, if any;
- establish manufacturing and supply chain capacity sufficient to provide clinical and, if applicable, commercial quantities of product candidates, including building our own manufacturing facility;
- establish a sales, marketing, internal systems and distribution infrastructure to commercialize any products for which we may obtain regulatory approval, if any, in geographies in which we plan to commercialize our products ourselves;
- maintain, expand, protect and enforce our intellectual property estate;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial, and support personnel, to execute our business plan and support our product development and potential future commercialization efforts;
- enter into collaborations or licenses for new technologies;
- make royalty, milestone, or other payments under our current and any future in-license agreements;
- incur additional legal, accounting, and other expenses in operating our business; and
- continue to operate as a public company.

#### **Impact of COVID-19 on our business**

The worldwide COVID-19 pandemic, including the identification of new variants of the virus, may affect our ability to initiate and complete preclinical studies, delay the initiation of our future clinical trials, or have other adverse effects on our business, results of operations, financial condition, and prospects. In addition, the pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could adversely affect our business, operations and ability to raise funds to support our operations.

To date, we have not experienced material business disruptions as a result of the pandemic. We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. To provide a safe work environment for our employees, we have implemented various measures to promote for social distancing, encourage employees to work remotely when possible, increase sanitization of our facilities and provide personal protective equipment for our employees. In addition, the third-party contract research organizations, or CROs, and contract development and manufacturing organizations, or CDMOs, that we engage have faced in the past and may face in the future disruptions that could affect our ability to initiate and complete preclinical studies, including disruptions in procuring items that are essential for our research and development activities, such as, for example, raw materials used in the manufacture of our product candidates and laboratory supplies for our preclinical studies, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic.

We cannot be certain what the overall impact of the COVID-19 pandemic, or the variants of the virus, will be on our business, and the pandemic has the potential to adversely affect our business, financial condition, results of operations, and prospects.

## Components of our results of operations

### **Revenue**

To date, we have not generated any revenue from product sales, and do not expect to generate any revenue from the sale of products for the foreseeable future. Our revenue to date has been generated through our collaboration agreement with PM (CF) Explorations, Inc., or PMCo, an affiliate of Flagship Pioneering (“Flagship”), in which we are entitled to receive reimbursement for the costs associated with our research activities performed.

### **Operating expenses**

#### *Research and development expenses*

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

- personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in research and development functions;
- expenses incurred in connection with the discovery and preclinical development of our research programs, including under agreements with third parties, such as consultants, contractors, CROs and CDMOs that manufacture material for use in our discovery and preclinical development;
- laboratory supplies and research materials;
- costs of licensing technology; and
- facilities, depreciation, and other expenses which include direct and allocated expenses.

We expense research and development costs as incurred. Costs for research and development activities are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

We do not track the research and development expenses on a program-by-program basis for our product candidates, and we do not allocate costs associated with our discovery efforts, laboratory supplies and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and the OMEGA platform. We use internal resources primarily to conduct our research and discovery activities as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and our technology platform and, therefore, we do not track these costs by program.

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

#### *General and administrative expenses*

General and administrative expenses consist primarily of salaries and other related costs such as bonuses and benefits, including stock-based compensation, for personnel in our executive, finance, legal, human resources, corporate business development, and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, information technology, auditing, tax, consulting

services, insurance, and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory, and tax compliance services, directors' and officers' liability insurance costs, and investor and public relations costs.

*Related party expense, net*

Related party expense, net consists primarily of fees paid to Flagship for their management services provided to us, as well as reimbursements for certain expenses, including insurance and benefits, partner and related fees, and software licenses incurred on our behalf. Additionally, our principal office and laboratory space is leased with an affiliate of Flagship, and we also sublease our other office and laboratory space to two other parties which are affiliates of Flagship. The rent expense and costs related to our principal office and laboratory space, including real estate taxes, insurance, and normal maintenance costs, are considered as related party expenses. Such related party expenses are offset with sublease income received from our related parties, which is comprised of base rent and costs related to the subleased premises such as real estate taxes, cost of operations, maintenance, repair, replacement, and property management.

***Other expense, net***

*Interest expense, net*

Interest expense, net primarily consists of interest payments as well as the amortization of the debt discount related to our loan and security agreement.

*Other expense, net*

Other expense, net primarily consists of the remeasurement gains or losses associated with changes in the fair value of the warrant liability and the success fee obligation related to our loan and security agreement, as amended. Until settlement, fluctuations in the fair value of our warrant liability and success fee obligation are based on the remeasurement at each reporting period.

**Results of operations**

***Comparison for the years ended December 31, 2021 and 2020***

The following table summarizes the results of our operations for the years ended December 31, 2021 and 2020, together with the changes in those items in thousands of dollars and as a percentage.

	Year ended December 31,		\$ Increase / (Decrease)	% Change
	2021	2020		
Collaboration revenue from related party	\$ 144	\$ —	\$ 144	100 %
Operating expenses:				
Research and development	47,865	21,063	26,802	127 %
General and administrative	16,603	6,236	10,367	166 %
Related party expense, net	1,708	1,346	362	27 %
Total operating expenses	66,176	28,645	37,531	131 %
Loss from operations	(66,032)	(28,645)	(37,387)	131 %
Other expense, net:				
Interest expense, net	(910)	(777)	(133)	17 %
Change in fair value of warrant liability	(1,310)	3	(1,313)	NM
Other expense, net	(28)	(28)	—	0 %
Total other expense, net	(2,248)	(802)	(1,446)	180 %
Net loss	\$ (68,280)	\$ (29,447)	\$ (38,833)	

NM - Not meaningful

#### Revenue

Revenue was \$0.1 million for the year ended December 31, 2021, which represented the reimbursement received for the costs of our research activities performed, in connection with the collaboration agreement with PMCo. There was no revenue for the year ended December 31, 2020.

#### Research and development expenses

Research and development expenses were \$47.9 million and \$21.1 million for the years ended December 31, 2021 and 2020, respectively. The following table summarizes our research and development expenses by nature (in thousands).

	Year ended December 31,	
	2021	2020
Personnel-related expenses	\$ 10,341	\$ 6,194
Discovery and preclinical development costs, including third-party costs (consultants, contractors, and CDMO)	24,235	6,528
Other research and development costs, including laboratory materials and supplies	7,093	4,930
Costs of licensing technology	1,833	686
Facilities and overhead expenses	4,363	2,725
Total research and development expenses	\$ 47,865	\$ 21,063

Research and development expenses increased by \$26.8 million to \$47.9 million for the year ended December 31, 2021, from \$21.1 million for the year ended December 31, 2020. The increase was primarily driven by the following:

- Increase of \$4.1 million in personnel-related expenses due to an increase in the number of employees in the research and development functions to support business growth.
- Increase of \$17.7 million in discovery and preclinical development costs and \$2.2 million in laboratory materials and supplies attributable to the increasing external manufacturing and research efforts to support the advancement of our pipeline and discovery portfolio, including the initiation of IND-enabling studies.
- Increase of \$1.1 million in costs of licensing technology primarily due to the option exercise fee incurred upon the execution of the first non-exclusive license agreement with Acuitas.

- Increase of \$1.6 million in facilities and overhead expenses due to higher overhead expenses allocated to the research and development functions as a result of an increase in headcount.

#### *General and administrative expenses*

General and administrative expenses increased by \$10.4 million to \$16.6 million for the year ended December 31, 2021, from \$6.2 million for the year ended December 31, 2020. The \$10.4 million increase was primarily driven by an increase of \$6.9 million in personnel-related expenses, including recruiting fees and the related stock-based compensation to support business growth. The remaining \$3.5 million increase is primarily attributable to higher legal, audit and consulting services and an increase in directors' and officers' liability insurance cost as a result of our IPO.

#### *Related party expense, net*

Related party expense, net was \$1.7 million and \$1.3 million for the years ended December 31, 2021 and 2020, respectively. The increase of \$0.4 million was primarily driven by the higher lease expense and related costs incurred for our principal office and laboratory space compared to the prior year period, in addition to certain fees payable to our non-employee directors after we became a public company.

#### *Interest expense, net*

Interest expense, net was \$0.9 million and \$0.8 million for the years ended December 31, 2021 and 2020, respectively. The increase of \$0.1 million was primarily attributed to the write-off of the unamortized debt discount attributed to the success fee obligation which we paid upon the closing of the IPO.

#### *Change in fair value of warrant liability*

During the year ended December 31, 2021, we recorded a \$1.3 million expense related to the change in fair value of warrant liability as compared to an immaterial amount of expense recorded for the year ended December 31, 2020, primarily as a result of the increase in the fair value of our common stock compared to the fair value of our preferred stock underlying the outstanding warrants. Upon the closing of the IPO, the warrants for the purchase of preferred stock automatically became warrants for the purchase of common stock and we reclassified the carrying value of the warrants from liability to additional paid-in capital in our balance sheet. In August 2021, the holders of such warrants completed a cashless exercise of the warrants, and we issued 82,193 shares of our common stock.

#### *Other expense, net*

Other expense, net was not significant for both of the years ended December 31, 2021 and 2020.

### **Liquidity and capital resources**

#### *Sources of liquidity*

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we support our continued research activities and development of our programs and platform. We have not yet commercialized any products, and we do not expect to generate product revenue for several years, if at all. To date, we have funded our operations primarily with proceeds from sales of equity securities, including our IPO, and borrowings under our loan and security agreement, as amended.

In August 2021, we completed our IPO pursuant to which we issued and sold 8,300,976 shares of our common stock, including 900,976 shares pursuant to the partial exercise of the underwriters' option to purchase additional shares, at a public offering price of \$17.00 per share, for aggregate gross proceeds of \$141.1 million. We received approximately \$128.1 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by us.

## Cash flows

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

	Year ended December 31,	
	2021	2020
Net cash used in operating activities	\$ (57,609)	\$ (26,133)
Net cash used in investing activities	(40,399)	(1,808)
Net cash provided by financing activities	261,539	48,618
Net increase in cash, cash equivalents, and restricted cash	163,531	20,677

### Operating activities

Net cash used in operating activities totaled \$57.6 million during the year ended December 31, 2021 compared to net cash used in operating activities of \$26.1 million during the year ended December 31, 2020. The \$31.5 million increase in operating cash outflows was primarily attributable to \$38.8 million higher net loss recognized during the year ended December 31, 2021, offset by the change in operating assets and liabilities and non-cash charges, consisting primarily of change in fair value of warrant liability and stock-based compensation expense.

### Investing activities

Net cash used in investing activities totaled \$40.4 million and \$1.8 million during the years ended December 31, 2021 and 2020, respectively. The increase was primarily attributable to the purchases of marketable securities beginning in December 2021.

### Financing activities

Net cash provided by financing activities for the year ended December 31, 2021 consisted primarily of the proceeds from our IPO of \$128.1 million, net of underwriting discounts and payments for offering costs, and net proceeds from the issuance of Series C redeemable convertible preferred stock of \$125.4 million in March 2021. Net cash provided by financing activities for the year ended December 31, 2020 consisted primarily of the net proceeds from the issuance of Series B redeemable convertible preferred stock of \$48.5 million during the period.

### Loan and security agreement

In March 2018, we entered into the loan and security agreement, or Loan Agreement, with Pacific Western Bank, or PWB, under which we borrowed \$8.0 million. In September 2019, we entered into an amendment to the Loan Agreement, or First Amendment, in which PWB made an additional term loan to us in an aggregate principal amount of \$12.0 million. The Loan Agreement was further amended in December 2020 to extend the principal repayment date.

In December 2021, we entered into an amendment to the Loan Agreement, or Fourth Amendment, in which PWB made an additional term loan to us in an aggregate principal amount of \$20.0 million. The proceeds of the Fourth Amendment were first applied to the repayment in full of all outstanding principal and accrued interest on the then outstanding term loan of \$12.0 million, and the remaining cash proceeds of \$8.0 million were used for general working capital and for capital expenditures purposes. The maturity date of the additional term loan will be on September 30, 2025, and it will be repaid beginning on September 30, 2023 in twenty-four equal monthly installments, including interest at a floating annual rate equal to the greater of (i) 0.50% above the prime rate then in effect and (ii) 5.50%, due monthly starting the first month after December 20, 2021. As of December 31, 2021, the interest rate applicable to the term loan was 5.50% and the interest payment on the outstanding term loan was less than \$0.1 million per month.

Borrowings under the Loan Agreement, as amended, are collateralized by substantially all of our personal property, other than our intellectual property. There are no financial covenants associated with the Loan Agreement, as amended; however, we are subject to certain affirmative and negative covenants to which we will remain subject to until maturity.



## **Funding requirements**

As of December 31, 2021, we had cash, cash equivalents, and marketable securities of \$225.3 million. We expect that our expenses will increase substantially in connection with our ongoing activities, particularly as we advance preclinical activities and into clinical trials for our product candidates in development. In addition, we will continue to incur additional costs associated with operating as a public company. The timing and amount of our operating and capital expenditures will depend largely on:

- the scope, progress, results, and costs of our preclinical studies and any future clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for our current and future product candidates in regions where we choose to commercialize any products;
- the number of future product candidates and potential additional indications that we may pursue and their development requirements;
- the stability, scale, yield, and cost of our manufacturing process as we scale-up production and formulation of our product candidates for clinical trials, in preparation for regulatory approval and in preparation for commercialization, including our ability to build our own manufacturing facility;
- the costs of pre- and post-commercialization activities for any approved product, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities;
- revenue, if any, received from commercial sales of our products, should any of our product candidates receive marketing approval;
- the costs and timing of changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs and timing of changes in the regulatory environment and enforcement rules;
- our ability to compete with other therapeutics in the indications we target;
- the effect of competing technological and market developments;
- the extent to which we enter into collaborations or licenses for products, product candidates, or technologies;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the costs of preparing, filing, and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims;
- the costs of operating as a public company; and
- the severity, duration, and impact of the COVID-19 pandemic, which may adversely impact our business.

We believe that the net proceeds from our IPO, together with our existing cash, cash equivalents, and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of the Annual Report. We have based this estimate on assumptions that may prove to be incorrect, and we could utilize our available capital resources sooner than we expect. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources.

## **Contractual obligations**

We enter into contracts in the normal course of business with CROs, CDMOs, and other third parties for preclinical research studies and testing and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation and in the case of certain arrangements with CROs and

CDMOs may include non-cancelable fees. The amount and timing of cancellation payments are not known until such time a contract is canceled.

We have also entered into license agreements with Flagship Pioneering Innovations V, Inc., Whitehead Institute for Biomedical Research, and Acuitas, under which we are obligated to make potential milestone payments, royalty payments, or both. Such payments are dependent upon the development of products using the intellectual property licensed under the agreements and are contingent upon the occurrence of future events; as such, the timing and likelihood of such potential obligations are not known with certainty.

As described previously, we borrowed an aggregate principal amount of \$20.0 million under the Loan Agreement, as amended. Pursuant to the terms of the Loan Agreement, as amended, interest payment on the outstanding term loan is less than \$0.1 million per month, and we are obligated to repay \$0.8 million of principal payment per month, beginning on September 30, 2023 until the maturity date of September 30, 2025.

In July 2020, we entered into a Shared Space Agreement with an affiliate of Flagship for our principal office and laboratory space. The Shared Space Arrangement commenced on August 1, 2020 and continues through July 31, 2022 with two options to extend the term for a period of 24 months each. Our lease payments for the remainder of the lease term will be approximately \$0.2 million per month. In January 2022, we entered into an amendment to modify certain terms of the Shared Space Agreement and exercise the option to renew the lease term for another 12 months. The lease term will now expire in July 2023. In connection with the modifications in the amendment, we have agreed to pay an upfront payment of \$2.9 million in the first quarter of 2022, which will cover the rent payment for the extended lease term.

We also have another office and laboratory space which was under a noncancelable lease agreement entered in 2017 and will expire in September 2024. Our lease payments for the remainder of the lease term will be approximately \$0.1 million per month. In September 2020, the space has been fully subleased to two other parties, which are affiliates of Flagship. The sublease agreements expire between 2021 and 2024.

In November 2021, we entered into a lease with ARE-MA Region No. 94, LLC to lease an aggregate of approximately 89,246 rentable square feet of office and laboratory space located at One Charles Park, Cambridge, Massachusetts, 02142. The term of the Lease is estimated to begin on December 15, 2022 and end on January 1, 2037, subject to certain extension rights. The base rent for the leased space will be \$115.00 per square foot, subject to an annual upward adjustment of 3% of the then current rental rate, starting on the first anniversary of the first payment of rent under the lease, and other potential adjustments based on our utilization of certain tenant improvement allowances. We intend to sublease a portion of this facility to supplement our growth plan.

### **Critical accounting policies and estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 2 - *Summary of Significant Accounting Policies* in the Notes to consolidated financial statements appearing at the end of this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

#### **Accrued research and development expenses**

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase

orders, communicating with our applicable 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 actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to vendors in connection with preclinical development activities, CROs in connection with research activities, and CDMOs in connection with the production of research materials.

We estimate accrued research and development expenses based on our estimates of the services received and efforts expended pursuant to quotes and contracts with third-party service providers, including CROs and CDMOs that supply, conduct and manage preclinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense, in which it will be evaluated for current or long-term classification based on when it is expected to be realized. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in changes in estimates that increase or decrease amounts recognized in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

### **Stock-based compensation**

We recognize all stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award, based on their fair values. Forfeitures are recognized as they occur. For stock option awards, the Company estimates the fair value on the date of the grant using the Black-Scholes option pricing model with the following inputs: (1) fair value of our common stock, (2) assumptions we make for the expected volatility of our common stock, (3) the expected term of our stock option awards, (4) the risk-free interest rate for a period that approximates the expected term of our stock option awards, and (5) our expected dividend yield, if any. Prior to our IPO in August 2021, there was no public market for our common stock. As a result, prior to our IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believes are relevant and which may have changed from the date of the most recent valuation through the date of the grant. Following our IPO, the fair value of our common stock is determined based on the quoted market price of our common stock. Additionally, due to the continued lack of sufficient company-specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us, including stage of product development and life science industry focus.

The assumptions included in the Black-Scholes option pricing model significantly affect our stock option valuations, and future changes in these assumptions could significantly change valuations of future stock option grants and, thus, affect future stock-based compensation expense. In addition, if circumstances were to change such that we determined stock options values were better represented by an alternative valuation method, such change could also significantly affect future stock-based compensation expense. To date, there have not been any material adjustments to our prior estimates included in the Black-Scholes option pricing model.

### **Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 - *Summary of Significant Accounting Policies* in the Notes to consolidated financial statements appearing at the end of this Annual Report.

## Emerging growth company and smaller reporting company status

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As a result, we may take advantage of specified reduced disclosure and other reporting requirements that are otherwise applicable generally to public companies. In particular, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we may adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

We are also a “smaller reporting company” as defined under the Securities Act and Exchange Act. We may continue to be a smaller reporting company so long as either (i) the market value of shares of our common stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of shares of our common stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company under the requirements of (ii) above, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

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

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 7A.

**Item 8. Financial Statements and Supplementary Data.**

The financial information required by Item 8 is located beginning on page F-1 of this report.

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

None.

**Item 9A. Controls and Procedures.**

*Limitations on effectiveness of controls and procedures*

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

*Evaluation of disclosure controls and procedures*

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of December 31, 2021, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on the evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2021, our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

*Management's annual report on internal control over financial reporting*

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) due to a transition period established by rules of the SEC for newly public companies.

This Annual Report on Form 10-K also does not include an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for "emerging growth companies".

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

PART III

**Item 10. Directors, Executive Officers and Corporate Governance.**

**Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics, or Code, that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the Code is available on the investor section of our website at [ir.omegatherapeutics.com](http://ir.omegatherapeutics.com). We intend to disclose on our website any amendments to, or waivers from, our Code that are required to be disclosed pursuant to SEC or Nasdaq rules. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report on Form 10-K.

**Executive Officers and Directors**

The information concerning our executive officers and directors required by this Item 10 is contained under the caption “Information about our Executive Officers and Directors” at the end of Part I of this Annual Report on Form 10-K.

The remainder of the information required by this Item 10 will be included in our definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2022 Annual Meeting of Stockholders under the headings “Corporate Governance,” “Delinquent Section 16(a) Reports” (if applicable) and “Committees of the Board” and is incorporated herein by reference.

**Item 11. Executive Compensation.**

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders under the headings “Executive and Director Compensation” and “Compensation Committee Interlocks and Insider Participation” (if applicable) and is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

**Securities Authorized for Issuance Under Equity Compensation Plans (as of December 31, 2021)**

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities in first column) (4)
Equity compensation plans approved by security holders (1)	5,476,484 (2)	\$ 4.90 (3)	2,961,751
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>5,476,484</b>		<b>2,961,751</b>

(1) Consists of the Omega Therapeutics, Inc. 2017 Equity Incentive Plan, as amended (the “2017 Plan”), the Omega Therapeutics, Inc. 2021 Incentive Award Plan (the “2021 Plan”) and the Omega Therapeutics, Inc. 2021 Employee Stock Purchase Plan (the “2021 ESPP”).

(2) Includes 4,844,040 outstanding options to purchase stock under the 2017 Plan and 632,444 outstanding options to purchase stock under the 2021 Plan.

- (3) As of December 31, 2021, the weighted average exercise price of outstanding options under the 2017 Plan was \$3.21 and the weighted average exercise price of outstanding options under the 2021 Plan was \$17.86.
- (4) Includes 2,481,751 shares available for future issuance under the 2021 Plan and 480,000 shares available for issuance under the 2021 ESPP. As of July 29, 2021, in connection with our initial public offering, no further grants are made under the 2017 Plan. The 2021 Plan provides for an annual increase to the number of shares available for issuance thereunder on the first day of each calendar year beginning on January 1, 2022 and ending on and including January 1, 2031, by an amount equal to the lesser of (i) 4% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by the our board of directors (but no more than 26,810,000 shares may be issued upon the exercise of incentive stock options). The 2021 ESPP provides for an annual increase to the number of shares available for issuance thereunder on the first day of each calendar year beginning on January 1, 2022 and ending on and including January 1, 2031, by an amount equal to the lesser of (i) 1% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by our board of directors, provided that no more than 6,450,000 shares of our common stock may be issued under the 2021 ESPP.

The remainder of the information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders under the heading "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders under the headings "Corporate Governance" and "Certain Relationships and Related Person Transactions" and is incorporated herein by reference.

**Item 14. Principal Accounting Fees and Services.**

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders under the heading "Independent Registered Public Accounting Firm Fees and Other Matters" and is incorporated herein by reference.



PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(a)(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(a)(3) Exhibits:

Exhibit Number	Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	<a href="#">Restated Certificate of Incorporation.</a>	8-K	001-40657	3.1	08/03/2021	
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	001-40657	3.2	08/03/2021	
4.1	<a href="#">Specimen Certificate of Common Stock.</a>	S-1/A	333-257794	4.2	07/26/2021	
4.2	<a href="#">Amended and Restated Investor Rights' Agreement, dated March 4, 2021.</a>	S-1/A	333-257794	4.1	07/26/2021	
4.3	<a href="#">Amended and Restated Warrant to Purchase Stock issued to PacWest Bankcorp, dated September 30, 2019, to purchase Series A preferred stock.</a>	S-1/A	333-257794	4.3	07/26/2021	
4.4	<a href="#">Description of Capital Stock.</a>					*
10.1#	<a href="#">Form of Indemnification Agreement between Omega Therapeutics, Inc. and its directors and officers.</a>	S-1/A	333-257794	10.8	07/26/2021	
10.2#	<a href="#">2021 Incentive Award Plan and form of agreements thereunder.</a>	S-1/A	333-257794	10.2	07/26/2021	
10.3#	<a href="#">2021 Employee Stock Purchase Plan.</a>	S-1/A	333-257794	10.3	07/26/2021	
10.4#	<a href="#">Non-Employee Director Compensation Program.</a>	S-1/A	333-257794	10.4	07/26/2021	
10.5#	<a href="#">Employment Agreement by and between Mahesh Karande and the Registrant, dated July 25, 2021.</a>	S-1/A	333-257794	10.17	07/26/2021	
10.6#	<a href="#">Employment Agreement by and between Thomas McCauley and the Registrant, dated July 24, 2021.</a>	S-1/A	333-257794	10.18	07/26/2021	
10.7#	<a href="#">Employment Agreement by and between Roger Sawhney and the Registrant, dated July 24, 2021.</a>	S-1/A	333-257794	10.19	07/26/2021	
10.8#	<a href="#">Employment Agreement by and between Yan Moore and the Registrant, dated December 12, 2021.</a>					*
10.9#	<a href="#">Consulting Agreement by and between Richard A. Young and the Registrant, dated November 7, 2016.</a>					*
10.10#	<a href="#">Amendment to Consulting Agreement by and between Richard A. Young and the Registrant, dated October 29, 2021.</a>					*
10.11	<a href="#">Fourth Amendment to Loan and Security Agreement, dated December 20, 2021.</a>	8-K	001-40657	10.1	12/21/2021	

10.12†	<a href="#">Non-Exclusive License Agreement between Acuitas Therapeutics, Inc. and the Registrant, dated March 22, 2021.</a>	S-1	333-257794	10.16	07/09/2021	
10.13	<a href="#">Lease Agreement between Omega Therapeutics, Inc. and ARE-MA Region No. 94, LLC.</a>					*
10.14	<a href="#">Amendment to Shared Space Agreement between Omega Therapeutics, Inc. and Senda Biosciences, Inc., dated January 31, 2022.</a>					*
21.1	<a href="#">Subsidiaries of the Registrant.</a>					*
23.1	<a href="#">Consent of Deloitte &amp; Touche LLP, Independent Registered Public Accounting Firm</a>					*
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>					*
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>					*
32.1*	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.</a>					**
32.2*	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.</a>					**
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					*

\* Filed herewith.

\*\* Furnished herewith.

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

#### 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, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Omega Therapeutics, Inc.

Date: March 10, 2022

By: \_\_\_\_\_  
/s/ Mahesh Karande  
**Mahesh Karande**  
**President and Chief Executive Officer**

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

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Mahesh Karande</u> <b>Mahesh Karande</b>	President, Chief Executive Officer and Director (principal executive officer)	March 10, 2022
<u>/s/ Roger Sawhney</u> <b>Roger Sawhney, M.D.</b>	Chief Financial Officer (principal financial officer and principal accounting officer)	March 10, 2022
<u>/s/ Noubar B. Afeyan</u> <b>Noubar B. Afeyan, Ph.D.</b>	Chairman of the Board of Directors	March 10, 2022
<u>/s/ David A. Berry</u> <b>David A. Berry, M.D., Ph.D.</b>	Director	March 10, 2022
<u>/s/ Luke M. Beshar</u> <b>Luke M. Beshar</b>	Director	March 10, 2022
<u>/s/ Elliott M. Levy</u> <b>Elliott M. Levy, M.D.</b>	Director	March 10, 2022
<u>/s/ John Mendlein</u> <b>John Mendlein, Ph.D., J.D.</b>	Director	March 10, 2022
<u>/s/ Mary T. Szela</u> <b>Mary T. Szela</b>	Director	March 10, 2022
<u>/s/ Richard A. Young</u> <b>Richard A. Young, Ph.D.</b>	Director	March 10, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<a href="#">Report of independent registered public accounting firm (PCAOB ID No. 34)</a>	F-2
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Omega Therapeutics, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Omega Therapeutics, Inc. and subsidiary (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2021 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

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

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

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

*/s/ Deloitte & Touche LLP*

Boston, Massachusetts

March 10, 2022

We have served as the Company's auditor since 2020.

**Omega Therapeutics, Inc.**  
**Consolidated balance sheets**

(in thousands, except share and per share amounts)

	December 31,	
	2021	2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 186,482	\$ 22,951
Marketable securities	38,845	—
Accounts receivable, due from related party	257	—
Prepaid expenses and other current assets	3,702	1,052
<b>Total current assets</b>	<b>229,286</b>	<b>24,003</b>
Property and equipment, net	3,605	3,482
Restricted cash	341	341
Other assets	101	257
<b>Total assets</b>	<b>\$ 233,333</b>	<b>\$ 28,083</b>
<b>Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 2,109	\$ 1,063
Accrued expenses	9,475	3,277
Other current liabilities	399	359
Long-term debt, current portion	—	3,000
<b>Total current liabilities</b>	<b>11,983</b>	<b>7,699</b>
Long-term debt, net	19,869	8,732
Other liabilities	853	1,055
<b>Total liabilities</b>	<b>32,705</b>	<b>17,486</b>
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, par value of \$0.001 per share; no shares and 57,125,232 shares authorized as of December 31, 2021 and December 31, 2020, respectively; no shares and 56,775,232 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	—	26,708
Series B redeemable convertible preferred stock, par value of \$0.001 per share; no shares and 50,000,000 shares authorized as of December 31, 2021 and December 31, 2020, respectively; no shares and 32,399,999 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	—	48,517
Series C redeemable convertible preferred stock, par value of \$0.001 per share; no shares authorized, issued and outstanding as of December 31, 2021 and December 31, 2020	—	—
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares and no shares authorized as of December 31, 2021 and December 31, 2020, respectively; no shares issued and outstanding as of December 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 200,000,000 and 137,700,000 shares authorized as of December 31, 2021 and December 31, 2020, respectively; 47,793,469 and 4,465,351 issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	48	5
Additional paid-in capital	335,147	1,592
Accumulated other comprehensive loss	(62)	—
Accumulated deficit	(134,505)	(66,225)
<b>Total stockholders' equity (deficit)</b>	<b>200,628</b>	<b>(64,628)</b>
<b>Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)</b>	<b>\$ 233,333</b>	<b>\$ 28,083</b>

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

**Omega Therapeutics, Inc.**  
**Consolidated statements of operations and comprehensive loss**  
(in thousands, except share and per share amounts)

	<b>Year ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Collaboration revenue from related party	\$ 144	\$ —
Operating expenses:		
Research and development	47,865	21,063
General and administrative	16,603	6,236
Related party expense, net	1,708	1,346
Total operating expenses	<u>66,176</u>	<u>28,645</u>
Loss from operations	(66,032)	(28,645)
Other expense, net:		
Interest expense, net	(910)	(777)
Change in fair value of warrant liability	(1,310)	3
Other expense, net	(28)	(28)
Total other expense, net	<u>(2,248)</u>	<u>(802)</u>
Net loss	<u>\$ (68,280)</u>	<u>\$ (29,447)</u>
Net loss per common stock attributable to common stockholders, basic and diluted	<u>\$ (3.05)</u>	<u>\$ (7.54)</u>
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	<u>22,404,058</u>	<u>3,906,168</u>
Comprehensive loss:		
Net loss	\$ (68,280)	\$ (29,447)
Other comprehensive loss:		
Unrealized loss on marketable securities	(62)	—
Comprehensive loss	<u>\$ (68,342)</u>	<u>\$ (29,447)</u>

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

**Omega Therapeutics, Inc.**  
**Consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit)**  
(in thousands, except share amounts)

	PREFERRED STOCK - SERIES A		PREFERRED STOCK - SERIES B		PREFERRED STOCK - SERIES C		COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	PAR VALUE	SHARES	PAR VALUE	SHARES	PAR VALUE	SHARES	PAR VALUE	CAPITAL	COMPREHENSIVE LOSS	DEFICIT	EQUITY (DEFICIT)
<b>As of January 1, 2020</b>	56,775,232	\$ 26,708	—	\$ —	—	\$ —	3,775,292	\$ 5	\$ 854	\$ —	\$ (36,778)	\$ (35,919)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$83	—	—	32,399,999	48,517	—	—	—	—	—	—	—	—
Issuance of common stock for options exercised	—	—	—	—	—	—	196,301	—	102	—	—	102
Vesting of restricted stock	—	—	—	—	—	—	496,322	—	—	—	—	—
Common stock repurchased	—	—	—	—	—	—	(2,564)	—	(1)	—	—	(1)
Stock-based compensation	—	—	—	—	—	—	—	—	637	—	—	637
Net loss	—	—	—	—	—	—	—	—	—	—	(29,447)	(29,447)
<b>As of December 31, 2020</b>	56,775,232	\$ 26,708	32,399,999	\$ 48,517	—	\$ —	4,465,351	\$ 5	\$ 1,592	\$ —	\$ (66,225)	\$ (64,628)
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of \$132	—	—	—	—	41,833,328	125,368	—	—	—	—	—	—
Issuance of common stock from initial public offering, net of issuance costs of \$13,005	—	—	—	—	—	—	8,300,976	8	128,104	—	—	128,112
Conversion of redeemable convertible preferred stock to common stock upon closing of initial public offering	(56,775,232)	(26,708)	(32,399,999)	(48,517)	(41,833,328)	(125,368)	34,678,733	35	200,559	—	—	200,594
Conversion of preferred stock warrant to common stock warrant upon closing of initial public offering	—	—	—	—	—	—	—	—	1,434	—	—	1,434
Cashless exercise of warrants	—	—	—	—	—	—	82,193	—	—	—	—	—
Issuance of common stock for options exercised	—	—	—	—	—	—	266,216	—	274	—	—	274
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(62)	—	(62)
Stock-based compensation	—	—	—	—	—	—	—	—	3,184	—	—	3,184
Net loss	—	—	—	—	—	—	—	—	—	—	(68,280)	(68,280)
<b>As of December 31, 2021</b>	—	\$ —	—	\$ —	—	\$ —	47,793,469	\$ 48	\$ 335,147	\$ (62)	\$ (134,505)	\$ 200,628

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



**Omega Therapeutics, Inc.**  
**Consolidated statements of cash flows**  
(in thousands)

	Year ended December 31,	
	2021	2020
<b>Operating activities</b>		
Net loss	\$ (68,280)	\$ (29,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,387	1,146
Amortization of debt issuance costs and debt discount	93	48
Accretion of discounts on marketable securities	25	—
Change in fair value of warrant liability	1,310	(3)
Change in fair value of success fee obligation	6	—
Non-cash interest expense	164	—
Stock-based compensation expense	3,184	637
Deferred rent	(157)	(107)
(Gain)/loss on disposal of equipment	(3)	28
Changes in operating assets and liabilities:		
Accounts receivable due from related party	(257)	—
Prepaid expenses and other current assets	(2,646)	(663)
Other assets	156	35
Accounts payable	1,040	138
Accrued expenses and other current liabilities	6,379	2,295
Other liabilities	(10)	(240)
Net cash used in operating activities	(57,609)	(26,133)
<b>Investing activities</b>		
Purchases of property and equipment	(1,467)	(1,808)
Purchase of marketable securities	(38,932)	—
Net cash used in investing activities	(40,399)	(1,808)
<b>Financing activities</b>		
Proceeds from issuance of redeemable convertible preferred stock	125,500	48,600
Payments for preferred stock issuance costs	(132)	(83)
Proceeds from initial public offering of common stock, net of commissions and underwriting discounts	131,238	—
Payments for initial public offering costs	(3,126)	—
Payment of success fee	(200)	—
Proceeds from debt financing	8,000	—
Payments of financing fees	(15)	—
Proceeds from exercise of stock options	274	101
Net cash provided by financing activities	261,539	48,618
<b>Net increase in cash, cash equivalents and restricted cash</b>	<b>163,531</b>	<b>20,677</b>
Cash, cash equivalents and restricted cash—beginning of period	23,292	2,615
Cash, cash equivalents and restricted cash—end of period	<u>\$ 186,823</u>	<u>\$ 23,292</u>
<b>Reconciliation of cash, cash equivalents and restricted cash</b>		
Cash and cash equivalents	\$ 186,482	\$ 22,951
Restricted cash	341	341
Cash, cash equivalents and restricted cash	<u>\$ 186,823</u>	<u>\$ 23,292</u>
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for interest	<u>\$ 754</u>	<u>\$ 732</u>
<b>Supplemental disclosure of noncash investing and financing activities</b>		
Conversion of preferred stock to common stock	<u>\$ 200,594</u>	<u>\$ —</u>
Reclassification of warrants to additional paid-in capital	<u>\$ 1,434</u>	<u>\$ —</u>
Purchase of property and equipment included accounts payable and accrued expenses	<u>\$ 44</u>	<u>\$ 23</u>
Fair value attributed to success fee obligation	<u>\$ 105</u>	<u>\$ 194</u>

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

## **1. Nature of the business and basis of presentation**

### ***Organization***

Omega Therapeutics, Inc. (the “Company” or “Omega”) is a development-stage biotechnology company pioneering a systematic approach to use mRNA therapeutics as programmable epigenetic medicines by leveraging its OMEGA Epigenomic Programming platform (“OMEGA platform”). The OMEGA platform harnesses the power of epigenetics, the mechanism that controls gene expression and every aspect of an organism’s life from cell genesis, growth and differentiation to cell death. The OMEGA platform enables control of fundamental epigenetic processes to correct the root cause of disease by restoring aberrant gene expression to a normal range without altering native nucleic acid sequences. The Company was incorporated in July 2016 (“inception”) as a Delaware corporation and its offices are in Cambridge, Massachusetts.

### ***Liquidity and going concern***

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

In August 2021, the Company completed its initial public offering (“IPO”) pursuant to which it issued and sold 8,300,976 shares of its common stock, including 900,976 shares pursuant to the partial exercise of the underwriters’ option to purchase additional shares, at a public offering price of \$17.00 per share, for aggregate gross proceeds of \$141.1 million. The Company received approximately \$128.1 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

The Company expects that its cash, cash equivalents, and marketable securities of \$225.3 million at December 31, 2021 will enable it to fund its operating expenses and capital expenditure requirements for at least twelve months from the filing date of the consolidated financial statements. However, additional funding will be necessary to fund future preclinical and clinical activities and to develop new product candidates. The Company expects to finance its future cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources.

### ***COVID-19-Related Significant Risks and Uncertainties***

With the global COVID-19 pandemic continuing throughout 2021, the Company is following, and plans to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. To provide a safe work environment for its employees, the Company has implemented various measures to promote for social distancing, encourage employees to work remotely when possible, increase sanitization of its facilities and provide personal protective equipment for its employees. The Company expects to continue incurring additional costs to ensure it adheres to the guidelines instituted by the federal, state and local governments and to provide a safe working environment to its onsite employees.

The extent to which the COVID-19 pandemic and variants of the virus impacts the Company’s business, its corporate development objectives, results of operations and financial condition, and the fair value of and market

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

While the COVID-19 pandemic did not significantly impact the Company's business or results of operations during the years ended December 31, 2021 and 2020, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on the Company's operations and financial condition.

### ***Basis of presentation***

The accompanying consolidated financial statements have been prepared in accordance 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 GAAP as found in the Accounting Standards Codification ("ASC"), and Accounting Standards Update ("ASU"), of the Financial Accounting Standards Board ("FASB"). All amounts herein are expressed in U.S. dollars ("USD") unless otherwise noted.

## **2. Summary of significant accounting policies**

### ***Principles of consolidation***

The accompanying consolidated financial statements include the accounts of Omega Therapeutics, Inc. and its wholly owned subsidiary, Omega Therapeutics Security Corporation, which is a Massachusetts subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

### ***Use of estimates***

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances.

Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the selection of useful lives of property and equipment, the fair values of certain financial instruments issued prior to the IPO (common stock, redeemable convertible preferred stock, and warrants), the fair value of the success fee obligation, and stock-based compensation. Actual results could differ from these estimates. Changes in estimates are reflected in reported results in the period in which they become known.

### ***Cash and cash equivalents***

Cash includes cash in readily available checking accounts, and cash equivalents include money market accounts and all highly liquid investments with an original maturity of three months or less from the date of purchase. Cash and cash equivalents are recorded at cost, which approximates fair value.

### ***Marketable securities***

The Company's marketable securities as of December 31, 2021 consisted of corporate debt securities and are classified as available-for-sale and are reported at fair value. Unrealized gains and losses on available-for-sale debt securities are reported as a component of accumulated other comprehensive loss in stockholders' equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included as a component in other expense, net.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's

ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge to the consolidated statements of operations and comprehensive loss.

### **Restricted cash**

Restricted cash represents collateral provided for letters of credit issued as security deposit in connection with the Company's office lease.

### **Concentrations of credit risk**

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

### **Guarantees and indemnifications**

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants, and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through December 31, 2021 and 2020, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related liabilities were established.

### **Property and equipment**

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

<u>Asset category</u>	<u>Estimated useful life</u>
Computer equipment and software	3 years
Laboratory equipment and office furniture	5 years
Leasehold improvements	Shorter of useful life or remaining lease term

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

### **Accrued research and development expenses**

The Company estimates accrued research and development expenses based on its estimates of the services received and efforts expended pursuant to quotes and contracts with third-party service providers, including contract research organizations ("CROs") and contract development and manufacturing organizations ("CDMOs") that supply, conduct and manage preclinical studies on the Company's 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 its vendors will exceed the level of services provided and result in a prepayment of the expense, in which it will be evaluated for current or long-term classification based on when it is expected to be realized. 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 estimate, the Company adjusts the accrual or the amount of prepaid expenses accordingly.

### ***Debt issuance costs***

Costs incurred in connection with the issuance of the Company's long-term debt have been recorded as a direct reduction against the debt and amortized over the life of the associated debt as a component of interest expense using the effective interest method.

### ***Warrant liability***

Warrants for the purchase of Series A redeemable convertible preferred stock ("Series A Preferred Stock") issued in connection with the loan and security agreement ("Loan Agreement"), as amended, with Pacific Western Bank ("PWB") were classified as a liability on the consolidated balance sheets at their fair value on the date of issuance. At the end of each reporting period, the change in estimated fair value during the period was recognized as a component of other expense, net in the consolidated statements of operations and comprehensive loss. The fair value of the warrants was remeasured at the end of each reporting period until the closing of the IPO, at which time the liabilities were reclassified to an equity component as the outstanding warrants automatically became warrants to purchase common stock.

### ***Success fee obligation***

The Loan Agreement, as amended, with PWB, requires the Company to pay a success fee ("success fee obligation") upon the occurrence of a specified liquidity event as described in the Loan Agreement, as amended. The Company determined that this obligation represented a freestanding derivative instrument. Accordingly, the success fee obligation was classified as a liability on the Company's consolidated balance sheets and initially recorded at fair value, with changes in fair value for each reporting period recognized in other expense, net in the consolidated statements of operations and comprehensive loss. The fair value of such obligation is remeasured at the end of each reporting period until the liability is settled.

### ***Deferred rent***

The Company's real estate operating leases provide for scheduled annual rent increases throughout the lease terms. The Company recognizes the effects of the scheduled rent increases on a straight-line basis over the full terms of the leases. Tenant improvement allowances, if any, provided by a landlord are recorded as deferred rent and amortized as reductions to rent expense over the lease terms.

### ***Equity issuance costs***

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations. Upon closing of the IPO, deferred offering costs were derecognized and recorded against the IPO proceeds as a reduction to additional paid-in capital. There were no deferred offering costs as of December 31, 2021 and 2020.

### ***Impairment of long-lived assets***

The Company evaluates its long-lived assets, which consist primarily of property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment losses recognized during the years ended December 31, 2021 and 2020.

## **Fair value measurements**

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

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

The fair value of the Company's cash and cash equivalents and restricted cash are measured through quoted market prices; the fair value of the Company's marketable securities is determined based on the pricing inputs other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date. Other current assets, accounts payable and accrued liabilities approximate their fair values as of December 31, 2021 and 2020, due to their short-term nature. The carrying value of the Company's debt approximates its fair value due to its variable interest rate, which approximates a market interest rate. The warrant liability and the success fee obligation associated with the Loan Agreement, as amended, contain unobservable inputs that reflect the Company's own assumptions in which there is little, if any, market activity at the measurement date, thus the Company's warrant liability and the success fee obligation are measured at their fair values on a recurring basis using unobservable inputs. See further discussion in Note 8, *Fair value of financial instruments*.

## **Redeemable convertible preferred stock**

The Company classified redeemable convertible preferred stock as temporary equity on the consolidated balance sheet because it could become redeemable upon occurrence of a deemed liquidation event that is outside of the Company's control. Upon completion of the Company's IPO, all of the Company's then outstanding Preferred Stock was automatically converted into common stock.

## **Revenue recognition**

Revenue recognized to-date is solely generated from the collaboration agreement with PM (CF) Explorations, Inc., or PMCo. The Company recognizes revenue in accordance with ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* and its related amendments, or, collectively, ASC 606.

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

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to

determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

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

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

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either (i) the customer simultaneously receives and consumes the benefits provided by the entity's performance, (ii) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or (iii) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer.

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from consideration allocated to the license when the license is transferred to the customer and the customer can use and benefit from the license. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

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

Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

### ***Research and development expenses***

Research and development expenses are charged to expense as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, consulting fees, cost of licensing technology, milestone payment, and external contract research and development and manufacturing expenses. Costs for certain research and development activities are recognized based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

### **Stock-based compensation**

The Company's stock-based compensation program allows for grants of incentive stock options, non-qualified stock options, stock appreciation rights, and restricted stock awards, restricted stock units and other stock-based awards to employees, directors and consultants.

The Company recognizes all stock-based compensation awards to employees and non-employees as expense in the consolidated statements of operations and comprehensive loss based on their fair values. For stock option awards, the Company estimates the fair value using the Black-Scholes option pricing model. The fair value of the Company's common stock is used to determine the fair value of restricted stock awards.

Stock-based compensation awards are subject to service vesting conditions, and forfeitures are recorded as they occur. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. The Company applies ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07"), in which the measurement date for non-employee awards is determined as the date of grant, and stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate, and (iv) expected dividends. Due to the lack of a public market for the Company's common stock prior to the IPO and continued lack of sufficient company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees and non-employees, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Due to the absence of an active market for the Company's common stock prior to the IPO, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the



factors used could result in different fair values of common stock at each valuation date. Subsequent to the IPO, the Company has used the quoted market price of its common stock on the measurement date.

### **Patent costs**

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred as patents have no future alternative use.

### **Income taxes**

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. As of December 31, 2021 and 2020, the Company has recorded a full valuation allowance against its deferred tax assets. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

### **Comprehensive loss**

Comprehensive loss is defined as the change in stockholders' equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss as well as other changes in stockholders' equity which includes certain changes in equity that are excluded from net loss. The Company's only element of other comprehensive loss is unrealized gains and losses on its marketable securities.

### **Net loss per share**

The Company follows the two-class method when computing net loss per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2021 and 2020.

## Segment and geographic information

Operating segments are defined as components of an entity about which discrete information is available for evaluation by the chief operating decision maker, or CODM, or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company's Chief Executive Officer. The CODM views its operations as and manages its business in one operating segment operating exclusively in the United States.

## Recently issued accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. As the Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jumpstart Our Business Startups Act ("JOBS Act"), the standard is effective for the Company beginning January 1, 2022. The Company adopted ASU 2016-02, and related amendments, on January 1, 2022 using the effective date transition method. The Company has also elected a package of practical expedients, under which an entity need not reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases, or initial direct costs for any existing leases. The Company also elected not to separate lease and non-lease components.

The Company has completed its initial assessment of the impact of ASU 2016-02 on the Company's consolidated financial statements and internal controls, including its evaluation of key policy elections. The Company's assessment included procedures to identify a complete lease population, performing analyses for each lease identified, assessing the differences in accounting that result from adopting this standard and assessing whether the Company meets certain practical expedients. While substantially complete, the Company is still in the process of finalizing its evaluation of the effect on the Company's financial statements, disclosures, and internal controls. The Company estimates its total assets and total liabilities on the consolidated balance sheet will increase by approximately \$3.5 million to \$5.5 million due to the recognition of right-of-use assets and lease liabilities upon adoption, net of the impact of eliminating existing deferred rent liabilities and unamortized tenant incentives related to its existing leasing arrangements. This estimated range is based on the Company's current lease portfolio but could be impacted by changes to the lease portfolio, including the total number of leases, lease commencement and end dates and lease termination expectations, as well as changes in anticipated lease incremental borrowing rates. The Company also anticipates changes to its disclosures to comply with the new disclosure requirements under the guidance.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes-Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes, enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. Adoption of the standard requires certain changes to be made prospectively and certain others to be made retrospectively. As the Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the JOBS Act, the standard is effective for the Company beginning January 1, 2022. The Company does not expect ASU 2019-12 to have a material effect on the Company's consolidated financial statements.

## 3. Marketable securities

The following table summarizes the Company's marketable securities (in thousands):

	December 31, 2021		
	Amortized cost	Gross unrealized losses	Fair value
Corporate debt securities	\$ 38,907	\$ (62)	\$ 38,845

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. At December 31, 2021, the balance in accumulated other comprehensive loss was comprised solely of activity related to marketable securities. There were no realized gains or losses recognized on the sale or maturity of marketable securities for the year ended December 31, 2021 and, as a result, the Company did not reclassify any amounts out of accumulated other comprehensive loss during the year.

The aggregate fair value of marketable securities that will be matured within 12 months of December 31, 2021 was \$21.6 million, and the aggregate fair value of marketable securities that will be matured after 12 months of December 31, 2021 was \$17.3 million. As of December 31, 2021, the Company did not intend to sell, and was more than likely not required to sell, the debt securities in a loss position before recovery of their amortized cost bases. As a result, the Company determined it did not hold any investments with any other-than-temporary impairment at December 31, 2021.

#### 4. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2021	2020
Prepaid rent	\$ 825	\$ —
Prepaid insurance	1,500	8
Prepaid software	143	78
Prepaid research and development	534	653
Prepaid other	436	120
Other receivables	264	193
Prepaid expenses and other current assets	\$ 3,702	\$ 1,052

#### 5. Property and equipment, net

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

	December 31,	
	2021	2020
Leasehold improvements	\$ 1,378	\$ 1,378
Lab equipment	4,822	3,444
Furniture and fixtures	1,073	985
Computer equipment	129	129
Construction in process	54	16
Total property and equipment	7,456	5,952
Less accumulated depreciation	(3,851)	(2,470)
Property and equipment, net	\$ 3,605	\$ 3,482

Depreciation expense for the years ended December 31, 2021 and 2020 was \$1.4 million and \$1.1 million, respectively.

## 6. Accrued expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2021	2020
Employee related expenses	\$ 2,545	\$ 1,124
Research costs	5,640	1,724
Professional and consulting fees	759	278
Interest	31	44
Other	500	107
Total	<u>\$ 9,475</u>	<u>\$ 3,277</u>

## 7. Term Loan

On March 9, 2018 (“Closing Date”), the Company entered into the Loan Agreement with Pacific Western Bank (“PWB”) to initially borrow \$8.0 million. In conjunction with the Loan Agreement, the Company issued a warrant to PWB to purchase up to 200,000 shares of Series A Preferred Stock at the strike price of \$0.50 per share. The warrant was exercisable for a 10-year period.

On September 30, 2019, the Company entered into an amendment to the Loan Agreement (the “First Amendment”), in which PWB made an additional term loan to the Company in an aggregate principal amount of \$12.0 million. In conjunction with the First Amendment, the Company also issued a warrant to purchase 350,000 shares of Series A Preferred Stock, which effectively restated and replaced the original warrant agreement. The strike price of the amended warrant is \$0.50 per share, and the term remains unchanged, expiring in March 2028. Refer to Note 8, *Fair value of financial instruments*, for further discussion on the valuation methodology and inputs for the determination of the fair value of the warrants. As the warrants issued were freestanding financial instruments that were exercisable for contingently redeemable shares, they were initially recorded at fair value on the date of issuance as a liability, with a corresponding discount recorded against the face value of the term loan. The discount was accreted against the face value of the term loan over its remaining term as additional interest expense. The change in estimated fair value of the warrants during the period was remeasured at each reporting date and recognized as a component of other expense, net in the consolidated statements of operations and comprehensive loss.

Upon the closing of the IPO, the Company’s outstanding warrants to purchase Series A Preferred Stock automatically became warrants to purchase an aggregate of 92,647 shares of common stock. As a result, the fair value of the warrants was reclassified to additional paid-in capital. Additionally, the remaining unamortized debt discount of \$0.1 million related to the warrants was written off during the three months ended September 30, 2021. In August 2021, the holders of such warrants completed a cashless exercise of the warrants, resulting in the Company’s issuance of 82,193 shares of its common stock, whereby 10,454 shares of common stock were withheld by the Company to pay for the exercise price of the warrants.

On January 22, 2020, the Loan Agreement was further amended (the “Second Amendment”) to extend the principal repayment start date. The Loan Agreement was further amended on December 30, 2020 (the “Third Amendment”) to extend the principal repayment date. The maturity date of the term loan was extended to June 30, 2023, and it was to be repaid beginning on June 30, 2021 in twenty-four equal installments, including interest at a floating annual rate equal to the greater of (i) 0.75% above the prime rate then in effect and (ii) 6.00%, due monthly starting the first month after December 30, 2020. As a result of the closing of Series C redeemable convertible preferred stock (“Series C Preferred Stock”) in March 2021, as further discussed in Note 12, *Redeemable convertible preferred stock*, the Company satisfied the cash proceeds milestone as defined in the Third Amendment, in which the Company received gross cash proceeds of more than \$50.0 million from the issuance of new preferred stock prior to June 30, 2021. Accordingly, the principal repayment date of the term loan was further extended to December 31, 2021 and the maturity date was extended to December 31, 2023. There

are no other changes to the terms as a result of the achievement of the cash proceeds milestone. In connection with the Third Amendment, the Company incurred \$15 thousand of debt issuance costs, which have been recorded as a direct reduction against the term loan and amortized over the life of the associated term loan as a component of interest expense using the effective interest method.

In accordance with the Third Amendment, the Company was required to pay a success fee of \$0.2 million upon the occurrence of a specified liquidity event, including an IPO. The Company determined that this obligation represented a freestanding financial instrument, and accordingly, the success fee obligation was classified as a liability on the Company's consolidated balance sheet as of December 31, 2020 and initially recorded at fair value, with changes in fair value for each reporting period recognized in other expense, net in the consolidated statements of operations and comprehensive loss. The fair value of such obligation was remeasured at the end of each reporting period until the liability was settled, for which it was settled and paid in August 2021 upon the completion of the IPO.

On December 20, 2021, the Company entered into an amendment to the Loan Agreement (the "Fourth Amendment"), in which PWB made an additional term loan in an aggregate principal amount of \$20.0 million. The proceeds of the term loan pursuant to the Fourth Amendment were first applied to the repayment in full of all outstanding principal and accrued interest on the then outstanding term loan of \$12.0 million; the remaining cash proceeds of \$8.0 million was used for general working capital and for capital expenditures purposes. The maturity date of the additional term loan will be on September 30, 2025, and it will be repaid beginning on September 30, 2023 in twenty-four equal monthly installments, including interest at a floating annual rate equal to the greater of (i) 0.50% above the prime rate then in effect and (ii) 5.50%, due monthly starting the first month after December 20, 2021. The Company incurred \$15 thousand of debt issuance costs, which was recorded as a direct reduction against the additional term loan and amortized over the life of the associated term loan as a component of interest expense using the effective interest method. Pursuant to the Fourth Amendment, the Company is also required to pay a success fee, ranging from \$0.1 million to \$0.2 million depending on the timing in achieving a specified liquidity event. The Company determined that this obligation represented a freestanding financial instrument, and it was classified as a liability on the Company's consolidated balance sheet as of December 31, 2021 and initially recorded at fair value, with changes in fair value for each reporting period recognized in other expense, net in the consolidated statements of operations and comprehensive loss. The fair value of such obligation is remeasured at the end of each reporting period until the liability is settled.

Borrowings under the Loan Agreement, as amended, are collateralized by substantially all of the Company's personal property, other than its intellectual property. There are no financial covenants associated with the Loan Agreement, as amended; however, the Company is subject to certain affirmative and negative covenants to which the Company will remain subject until maturity.

As of December 31, 2021, the full amount of \$20.0 million of the term loan was classified long-term based on the repayment start date. As of December 31, 2020, the long-term debt, current portion was \$3.0 million and the long-term debt was \$9.0 million. The Company's outstanding term loan balance was comprised of the following (in thousands):

	December 31,	
	2021	2020
Principal	\$ 20,000	\$ 12,000
Unamortized debt discount	(131)	(268)
Net carrying amount	\$ 19,869	\$ 11,732

The Company determined that the expected life of the debt was equal to the term on the term loan. The effective interest rate on the liability component ranged from 5.53% to 7.51% for the period from the date of issuance through December 31, 2021. The following table sets forth total interest expense recognized related to the term loan (in thousands):

	Year ended December 31,	
	2021	2020
Contractual interest expense	\$ 740	\$ 732
Amortization of debt issuance costs and debt discount	258	48
Total interest expense	\$ 998	\$ 780

As of December 31, 2021 and 2020, accrued interest on the term loan was \$31 thousand and \$44 thousand, respectively.

The Company is required to repay the following principal amounts in connection with its term loan (in thousands):

2022	\$	—
2023		2,500
2024		10,000
2025		7,500
	<u>\$</u>	<u>20,000</u>

## 8. Fair value of financial instruments

The fair value of the Company's financial instruments is summarized in the tables below (in thousands):

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
<b>Financial Assets</b>				
Money market funds	\$ 110,864	\$ —	\$ —	\$ 110,864
Marketable securities	—	38,845	—	38,845
Total	<u>\$ 110,864</u>	<u>\$ 38,845</u>	<u>\$ —</u>	<u>\$ 149,709</u>
<b>Financial Liabilities</b>				
Success fee obligation	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 105</u>	<u>\$ 105</u>

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
<b>Financial Liabilities</b>				
Warrant liability	\$ —	\$ —	\$ 124	\$ 124
Success fee obligation	—	—	194	194
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 318</u>	<u>\$ 318</u>

The Company's warrant liability and success fee obligation contain unobservable inputs that reflected the Company's own assumptions in which there is little, if any, market activity at the measurement date. Accordingly, the Company's warrant liability and success fee obligation are measured at fair value on a recurring basis using unobservable inputs at each reporting period and are classified as Level 3 inputs. As of December 31, 2021, the fair value of the Company's warrant liability was zero as the warrants became warrants to purchase common stock upon the closing of the IPO. As of December 31, 2020, the warrant liability was recorded as other liabilities on the consolidated balance sheet as it was deemed more probable than not by the Company to be settled in longer than one year.

The fair value of the warrants was estimated using the Black-Scholes option-pricing model. The expected term represented the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The expected dividend was zero as the Company had not paid any dividends on its common stock. The Company was a private company and lacked company-specific historical and implied volatility information of its stock. Therefore, it estimated its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants.

The assumptions used in the Black-Scholes option-pricing model for the warrants were as follows:

	August 3, 2021	December 31, 2020
Expected volatility	77.03 - 77.62%	73.09 - 77.79%
Risk-free interest rate	0.95 - 1.40%	0.58 - 0.65%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.6 - 6.9	7.2 - 7.9

The fair value of the warrants was remeasured at each reporting period, with changes in fair value recognized in the consolidated statements of operations and comprehensive loss, until the warrants were settled in August 2021. The change in the fair value of the warrant liability during the year ended December 31, 2021 was \$1.3 million; and there was an immaterial change in the fair value of the warrant liability for the year ended December 31, 2020.

The fair value of the success fee obligation was determined using the probability-weighted expected return method. The key estimates and assumptions impacting the fair value included the probability of achieving a specified liquidity event, the expected timing of achieving a liquidity event and discount rate. The fair value of the success fee obligation was remeasured at each reporting period, with changes in fair value recognized in the consolidated statements of operations and comprehensive loss, until such liability was settled. As a result of the completion of the IPO, the Company paid \$0.2 million of the success fee pursuant to the Third Amendment, and the related liability was zero as of December 31, 2021. In accordance with the Fourth Amendment, the Company will be required to pay a success fee upon the achievement of certain liquidity event; accordingly, the related obligation is recorded as current liabilities on the consolidated balance sheet as it is deemed more probable than not by the Company to be settled in less than one year.

The following reflects the significant quantitative inputs used to determine the valuation of the success fee obligations:

	Year ended December 31,	
	2021	2020
Discount rate	5.5%	6.0%
Expected timing of achieving liquidity events (years)	0.6 - 1.8	0.5 - 1
Probability of achieving liquidity events	10% - 90%	1% - 99%

The following table provides a roll-forward of the fair values of the Company's warrant liability and the success fee obligation for which fair value is determined by Level 3 inputs (in thousands):

	Warrant liability	Success fee obligation from the Third Amendment	Success fee obligation from the Fourth Amendment
Fair value as of January 1, 2020	\$ 127	\$ —	\$ —
Initial fair value of success fee obligation	—	194	—
Change in fair value	(3)	—	—
Fair value as of December 31, 2020	124	194	—
Initial fair value of success fee obligation	—	—	105
Change in fair value	1,310	6	—
Reclassification to additional paid-in-capital in connection with IPO	(1,434)	—	—
Settlement of success fee obligation	—	(200)	—
Fair value as of December 31, 2021	\$ —	\$ —	\$ 105

## 9. Commitments and contingencies

### Operating leases

In 2017, the Company entered a noncancelable operating lease agreement to lease its office space at 325 Vassar Street, Cambridge, Massachusetts, which will expire in September 2024. The Company is required to pay property taxes, insurance, and normal maintenance costs. The operating lease contains predetermined fixed escalations of minimum rentals during the lease term. During 2018, the Company received \$1.1 million of landlord-funded leasehold improvements related to the leased office space. The landlord-funded leasehold improvements were recorded as property and equipment, net and deferred rent in the consolidated balance sheets and are being amortized as a reduction to rent expense over the life of the lease. In 2019 and 2020, the Company entered into sublease agreements with two related parties to sublease this office and laboratory space. Refer to Note 17, *Related party transactions*, for further details.

On July 13, 2020, the Company entered into a Shared Space Arrangement (“the Arrangement”) with Senda Biosciences (“Senda”, also formerly known as Kintai Therapeutics, Inc.) to share one-third of Senda’s 69,867 square feet of leased space at 20 Acorn Park Drive, Cambridge, Massachusetts. Senda is a related party as it is an affiliate of Flagship Pioneering (“Flagship”). The Arrangement commenced on August 1, 2020 and continues through July 31, 2022 with two options to extend the term of the Arrangement for a period of 24 months each. The operating lease contains predetermined fixed escalations of minimum rentals during the lease term, and the Company is required to pay property taxes, insurance, and normal maintenance costs. During the years ended December 31, 2021 and 2020, the Company incurred rental expenses of \$2.6 million and \$1.0 million, respectively. As of December 31, 2021 and 2020, the Company did not have any outstanding payments due to Senda.

In January 2022, the Company entered into an amendment to the Arrangement with Senda to exercise the option to renew the lease term for another 12 months. The lease term will now expire in July 2023. The Company also modified certain provisions related to the extension term. In connection with the modifications in the amendment, the Company will pay an upfront payment of \$2.9 million, which will cover the rent payment for the extended lease term. Additionally, upon the expiration of the lease term, the Company will receive \$0.7 million from Senda for all furniture, fixtures and equipment owned by the Company that will remain at the lease property.

The Company recognizes the rental expense on a straight-line basis over the life of the respective lease from the date the Company takes possession of the office and records the difference between amounts charged to operations and amounts paid as deferred rent. Rent expense under both lease agreements for the years ended December 31, 2021 and 2020 was \$3.3 million and \$2.2 million, respectively.

As of December 31, 2021, the future minimum lease payments for the Company’s facility operating leases for each of the years ending December 31 were as follows (in thousands):

2022	\$	3,013
2023		10,711
2024		11,766
2025		10,879
2026		11,205
Thereafter		148,290
Total minimum lease payments	\$	<u>195,864</u>

On November 4, 2021, the Company entered into a lease with ARE-MA Region No. 94, LLC to lease an aggregate of approximately 89,246 rentable square feet of office and laboratory space located at One Charles Park, Cambridge, Massachusetts, 02142. The term of the lease is estimated to begin on December 15, 2022 and end on January 1, 2037, subject to certain extension rights. The base rent for the leased space will be \$115.00 per square foot, subject to an annual upward adjustment of 3% of the then current rental rate, starting on the first anniversary of the first payment of rent under the lease, and other potential adjustments based on the Company’s utilization of certain tenant improvement allowances. In accordance with the lease agreement, the Company paid



\$0.8 million upon the execution of the lease, which will offset the first month's rent. As of December 31, 2021, the future minimum non-cancelable lease payments amount to approximately \$190.5 million over the lease term are reflected in the table above.

## 10. License agreements

### ***Flagship Pioneering Innovations V, Inc.***

In March 2019, the Company entered into an exclusive license agreement with Flagship Pioneering Innovations V, Inc., an affiliate of Flagship, under which the Company was granted an exclusive, worldwide, royalty-bearing, sublicensable, transferable license under specified patent rights to develop, manufacture and commercialize licensed products (the "Flagship License"). Under the terms of the Flagship License, the Company is obligated to pay low single digit percentage royalties on net sales of licensed products by the Company. Royalties shall be paid by the Company on a country-by-country basis until expiration or abandonment of the last valid patent claim covering such licensed product in such country. The Company is also obligated to reimburse Flagship for patent prosecution costs.

The royalty payment is contingent upon sales of licensed products under the Flagship License. As such, when such expense is considered probable and estimable at the commencement of sales, the Company will account for the royalty expense as cost of sales for the amount it is obligated.

### ***Whitehead Institute for Biomedical Research***

In May 2019, the Company entered into an exclusive license agreement with the Whitehead Institute for Biomedical Research ("WIBR"), an affiliate of one of the Company's board members, under which the Company was granted an exclusive, worldwide, royalty-bearing, sublicensable license under specified patent rights to research, make, have made, use, sell, offer to sell, lease and import products and to perform and have performed licensed processes (the "WIBR Exclusive License"). Under the terms of the WIBR Exclusive License, the Company paid a nonrefundable upfront fee of less than \$0.1 million upon the commencement of the exclusive license agreement. The Company is obligated to pay WIBR annual license maintenance fees of less than \$0.1 million and low single digit percentage royalties on net sales of licensed products by the Company and its affiliates and sublicensees. Additionally, the Company is required to make milestone payments of up to \$1.7 million in the aggregate for each of the first three licensed products (excluding backup products) upon the achievement of specified clinical and regulatory milestones. In addition, the Company is required to pay to WIBR a percentage of the non-royalty payments that it receives from sublicensees of the WIBR Exclusive License. This percentage ranges from zero to low double-digits and will be based upon the stage of development of the licensed product at the time such sublicense is executed.

In May 2019, the Company also entered into a co-exclusive license agreement with WIBR under which the Company was granted a co-exclusive, worldwide, royalty-bearing, sublicensable license under specified patent rights to research, make, have made, use, sell, offer to sell, lease and import products and to perform and have performed licensed processes (the "WIBR Co-Exclusive License"). Under the terms of the WIBR Co-Exclusive License, the Company paid a nonrefundable upfront fee of less than \$0.1 million upon the commencement of the co-exclusive license agreement. The Company is obligated to pay WIBR annual license maintenance fees of less than \$0.1 million and sub single digit percentage royalties on net sales of licensed products by the Company and its affiliates and sublicensees as well as low single digit percentage royalties on licensed service income received by the Company and its affiliates. Additionally, the Company is required to make milestone payments of up to \$1.9 million in the aggregate for each of the first three licensed products (excluding backup products) upon the achievement of specified clinical, regulatory, and sublicensing milestones. In addition, the Company is required to pay to WIBR annual fees of less than \$0.1 million for each sublicense agreement.

During the year ended December 31, 2021, the Company recognized expense of \$0.1 million for the license maintenance fees, milestone payment, and the reimbursable patent costs under the agreements. The milestone obligation was incurred upon the achievement of a milestone event pursuant to the exclusive license agreement. During the year ended December 31, 2020, the Company recognized expense of \$0.1 million for the license maintenance fees and the reimbursable patent costs under the agreements. There was an immaterial amount of outstanding payment due to WIBR as of December 31, 2021, and there was no outstanding payment due to WIBR as of December 31, 2020.

The annual maintenance fees are recorded as an expense on an annual basis based on the stated amount for the applicable year. Upon determination that a milestone payment is probable to occur, the amount due will be recorded as research and development. As mentioned above, a milestone event was achieved during the year ended December 31, 2021, and the related milestone payment was recorded as research and development expense during the period. As the triggering of these milestone payments was not considered probable during 2020, no expense has been recorded for these milestones during the year ended December 31, 2020.

The royalty payments and the sublicense non-royalty payments are contingent upon sales of license products or execution of a sublicense agreement under the WIBR Exclusive and Co-Exclusive Licenses. As such, when such expenses are considered probable and estimable at the commencement of sales or execution of a sublicense agreement, the Company will accrue royalty expense and sublicense non-royalty payments, as applicable, for the amount the Company is obligated.

#### ***Acuitas Therapeutics, Inc.***

In October 2020, the Company entered into a development and option agreement (the "Development and Option Agreement") with Acuitas Therapeutics, Inc. ("Acuitas"). Under the terms of the Development and Option Agreement, the parties agreed to jointly develop certain products combining the Company's gene modulating therapeutics with Acuitas' lipid nanoparticles. Additionally, in accordance with the Development and Option Agreement, the Company has options to obtain non-exclusive, worldwide, sublicensable licenses under Acuitas' patents and know-how related to lipid nanoparticle technology ("Acuitas LNP Technology") with respect to two specified targets (e.g., OEC constructs) ("Reserved Targets") to develop and commercialize one or more therapeutic products relating to such targets. For each option and Reserved Target, the Company is obligated to pay an annual technology access fee and target reservation and maintenance fees collectively in the low-mid six figures until such Reserved Target is removed from the Reserved Target list or until the Company exercises an option with respect to such Reserved Target. In the event that the Company exercises the options, the Company will pay \$1.5 million for the first non-exclusive license and \$1.75 million for the second non-exclusive license. Under the terms of the Development and Option Agreement, the Company is also responsible for the full-time equivalent ("FTE") funding obligations, which is expected to be approximately \$0.4 million per year, and reimbursements to Acuitas for certain development and material costs incurred by them.

In March 2021, the Company exercised the first option under the Development and Option Agreement and entered into a non-exclusive license agreement with Acuitas (the "Acuitas License Agreement") under which the Company was granted a non-exclusive, worldwide, sublicensable license under the Acuitas LNP Technology to research, develop, manufacture, and commercially exploit products consisting of the Company's gene modulating therapeutics and Acuitas' lipid nanoparticles. In connection with the option exercise, the Company incurred an expense for the option exercise fee of \$1.5 million. Under the Acuitas License Agreement, the Company is required to pay Acuitas an annual license maintenance fee in the high six figures until the Company achieves a certain development milestone. Acuitas is entitled to receive potential clinical and regulatory milestone payments of up to \$18.0 million in the aggregate. With respect to the sale of each licensed product, the Company is also obligated to pay Acuitas low single digit percentage royalties on net sales of the licensed products by the Company and its affiliates and sublicensees in a given country until the last to occur, in such country, of (i) the expiration or abandonment of all licensed patent rights covering the licensed product, (ii) expiration of any regulatory exclusivity for the licensed product, or (iii) ten years from the first commercial sale of the licensed product.

During the year ended December 31, 2021, the Company recorded an aggregate of \$3.3 million of research and development expenses, consisting of the expenses incurred for the option exercise fee, technology access fees, target reservation and maintenance fees, the costs of services performed by Acuitas, the material costs and the reimbursable costs. During the year ended December 31, 2020, the Company recorded an aggregate of \$0.8 million of research and development expenses, consisting of the expenses incurred for technology access fees, target reservation and maintenance fees, and the costs of services performed by Acuitas, the material costs and the reimbursable costs.

The option exercise fee under the Development and Option Agreement was recorded as research and development expense upon the Company's exercise of the first option. Additionally, the technology access fees, target reservation and maintenance fees, expenses associated with the FTE funding obligations and reimbursements for development and material costs incurred by Acuitas are recorded as research and

development expense when incurred. The annual maintenance fee will be recorded as an expense on an annual basis based on the stated amount for the applicable year. Upon determination that a milestone payment is probable to occur, the amount due will be recorded as research and development expense. As the triggering of these milestone payments was not considered probable during the year ended December 31, 2021, no expense has been recorded for these milestones during the period. The royalty payment is contingent upon sales of licensed products under the Acuitas License Agreement, and when such expenses are considered probable and estimable at the commencement of sales, the Company will accrue royalty expense for the amount the Company is obligated.

## **11. Collaboration agreement**

In November 2021, the Company entered into a five-year collaboration agreement with PMCo, an affiliate of Flagship, under which PMCo was granted an exclusive license covering specified patent rights of the Company's lipid nanoparticle technology to develop one or more therapeutic products to treat diseases related to the cystic fibrosis transmembrane conductance regulator gene, like cystic fibrosis. Under the terms of the agreement, the Company will perform certain research activities in accordance with the research plan, and PMCo will be solely responsible for, at its sole cost and expense, and will have sole discretion with respect to, developing, manufacturing, seeking regulatory approval for and commercializing licensed products. The Company expects to receive approximately \$3.5 million in cost reimbursement over the course of the next two to three years to fund the related research and development activities. The research plan funding may be adjusted upon mutual written agreement from both parties. Additionally, in the event PMCo is acquired or sold, the Company is entitled to receive a portion of the proceeds of such transaction, subject to various reductions and other amounts payable in accordance with the agreement.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, PMCo, is a customer. The Company determined that the research activities and the exclusive license granted under the collaboration agreement is considered as a single performance obligation, and therefore, the transaction price was allocated entirely to the single performance obligation. The Company recognizes revenue related to the single performance obligation over time as the underlying services are performed and/or external costs are incurred.

The transaction price as of the inception of the contract was determined to be \$3.5 million based on the estimated required efforts to fulfill the performance obligation. As of December 31, 2021, the remaining transaction price is estimated to be \$3.4 million, which is expected to be recognized as revenue through 2024.

The Company recognized funded research and collaboration revenue of \$0.1 million in the consolidated statement of operations and comprehensive loss during the year ended December 31, 2021. Additionally, the Company recognized \$0.1 million of current deferred revenue as of December 31, 2021 based on the period the services are expected to be performed and/or related costs to be incurred. Costs incurred associated with collaboration agreement was recorded as research and development expenses.

Pursuant to the agreement, we are entitled to receive a portion of the sales proceeds in the event PMCo is acquired or sold. At the end of each reporting period, the Company evaluates the probability of occurrence of such transaction. As of December 31, 2021, the Company determined that the proceeds from such transaction was not probable of recognition.

## **12. Redeemable convertible preferred stock**

During August 2017 and March 2021, the Company issued Series A, Series B and Series C Preferred Stock (collectively the "Preferred Stock") to investors in private placements. Upon completion of the Company's IPO, all of the Company's then outstanding Preferred Stock was automatically converted into an aggregate of 34,678,733 shares of common stock.

### ***Series A Redeemable Convertible Preferred Stock***

During 2017 and 2019, the Company issued an aggregate of 56,775,232 shares of Series A Preferred Stock at a purchase price of \$0.50 per share in exchange for cash proceeds of \$25.5 million and the exchange of approximately \$2.8 million in outstanding promissory notes, including \$54 thousand in accrued interest. In

connection with the issuance of Series A Preferred Stock during 2017 and 2019, the Company incurred less than \$0.1 million of issuance costs. No additional shares of Series A Preferred Stock were issued after 2019.

### **Series B Redeemable Convertible Preferred Stock**

On January 27, 2020, the Company issued 24,066,666 shares of Series B Preferred Stock at a purchase price of \$1.50 per share for aggregate proceeds of \$36.1 million. On June 2, 2020, the Company issued an additional 3,333,333 shares of Series B Preferred Stock at the purchase price of \$1.50 per share for aggregate proceeds of \$5.0 million. On August 3, 2020, the Company issued 5,000,000 shares of Series B Preferred Stock at the purchase price of \$1.50 per share for aggregate proceeds of \$7.5 million. No additional shares of Series B Preferred Stock were issued after August 2020. In connection with the issuance of Series B Preferred Stock in 2020, the Company incurred \$83 thousand of issuance costs.

### **Series C Redeemable Convertible Preferred Stock**

In March 2021, the Company issued an aggregate of 41,833,328 shares of Series C Preferred Stock, at a price of \$3.00 per share, for gross proceeds of \$125.5 million. The terms of the Series C Preferred Stock are substantially the same as the terms of the Series A and Series B Preferred Stock. No additional shares of Series C Preferred Stock were issued after March 2021. In connection with the issuance of Series C Preferred Stock in March 2021, the Company incurred \$0.1 million of issuance costs. The Company further amended its Amended and Restated Certificate of Incorporation to increase the authorized preferred stock issuable from 107,125,232 shares to 132,858,564 shares.

As of December 31, 2020, the Preferred Stock consisted of the following (in thousands, except for share data):

	December 31, 2020				
	Preferred Stock Authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A Preferred Stock	57,125,232	56,775,232	\$ 26,708	\$ 25,500	15,028,741
Series B Preferred Stock	50,000,000	32,399,999	48,517	48,600	8,576,470
	<u>107,125,232</u>	<u>89,175,231</u>	<u>\$ 75,225</u>	<u>\$ 74,100</u>	<u>23,605,211</u>

### **13. Preferred and common stock**

The Company's board of directors and stockholders approved an amendment to the Company's certificate of incorporation, which became effective on July 23, 2021. The amendment, among other things, effected a 1-for-3.777776 reverse stock split of the Company's issued and outstanding common stock, a proportional adjustment to the conversion price for Series A, B and C Preferred Stock and to the exercise prices and number of shares of common stock underlying the outstanding stock options. All share, per share and additional paid in capital amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

In August 2021, the Company completed its IPO pursuant to which it issued and sold 8,300,976 shares of its common stock, including 900,976 shares pursuant to the partial exercise of the underwriters' option to purchase additional shares, at a public offering price of \$17.00 per share, for aggregate gross proceeds of \$141.1 million. The Company received approximately \$128.1 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In connection with the completion of the IPO, the Company's board of directors and stockholders approved the Company's Amended and Restated Certificate of Incorporation to, among other things, provide for 200,000,000 authorized shares of common stock with a par value of \$0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of \$0.001 per share.

The holders of common stock are entitled to one vote for each share of common stock. Subject to the payment in full of all preferential dividends to which the holders of the preferred stock are entitled, the holders of

common stock shall be entitled to receive dividends out of funds legally available. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, after the payment or provision for payment of all debts and liabilities of the Company and all preferential amounts to which the holders of preferred stock are entitled with respect to the distribution of assets in liquidation, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

As of December 31, 2021, the Company has reserved an aggregate of 5,476,484 shares of common stock for the potential exercise of outstanding stock options under its equity incentive plans. Upon the effectiveness of the 2021 Incentive Award Plan ("2021 Plan"), the Company ceased granting awards under the 2017 Equity Incentive Plan ("2017 Plan"), and the 4,844,040 shares of common stock subject to outstanding stock options issued under the 2017 Plan may become available for future issuance under the 2021 Plan to the extent such stock options are forfeited.

#### **14. Equity incentive plan**

##### ***2017 Equity Incentive Plan***

In June 2017, the Company's board of directors adopted the 2017 Plan, which provided for the grant of qualified incentive stock options and nonqualified stock options, restricted stock or other awards to the Company's employees and non-employees for the issuance or purchase of shares of the Company's common stock. As of December 31, 2021, there were no shares available for future grants under the 2017 Plan and a total of 4,844,040 shares of the Company's common stock were subject to outstanding stock options issued under the 2017 Plan.

The 2017 Plan is administered by the Company's board of directors or a committee thereof to the extent the Company's board of directors has delegated its power or authority under the 2017 Plan. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common stock on the date of grant. Stock options awarded under the 2017 Plan expire 10 years after the grant date unless the board of directors sets a shorter term. Incentive stock options and nonqualified stock options granted to employees and non-employees typically vest over four years. Certain stock options provide for accelerated vesting if there is a change in control, as defined in the 2017 Plan.

##### ***2021 Incentive Award Plan***

The Company's board of directors adopted, and the Company's stockholders approved the 2021 Plan in July 2021. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards, and subsequent to the IPO, all equity-based awards are granted under the 2021 Plan. The Company initially reserved 2,960,000 shares of its common stock for future issuance under the 2021 Plan, and such number of shares of common stock is subject to an annual increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2023, equal to the lesser of (i) 4% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by the board of directors. As of December 31, 2021, there were 2,481,751 shares available for future grants under the 2021 Plan, and a total of 632,444 shares of the Company's common stock were subject to outstanding stock options issued under the 2021 Plan.

In December 2021, the Company's compensation committee approved that the number of shares of its common stock for future issuance under the 2021 Plan to be increased by 4% of the aggregate number of common stock outstanding at December 31, 2021. Such increase was effective on January 1, 2022.

For the years ended December 31, 2021 and 2020, the Company recorded stock-based compensation expense of \$3.2 million and \$0.6 million, respectively, allocated to research and development and general and

administrative expenses in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year ended December 31,	
	2021	2020
Research and development	\$ 1,205	\$ 299
General and administrative	1,979	338
Total stock-based compensation expense	\$ 3,184	\$ 637

### Stock options

The assumptions used in the Black-Scholes option-pricing model for stock options granted were as follows:

	Year ended December 31,	
	2021	2020
Expected volatility%	76.73% - 80.18%	72.44 - 79.02%
Weighted-average risk-free interest rate%	1.12 %	1.00 %
Expected dividend yield%	0.00 %	0.00 %
Weighted-average expected term (in years)	6.09	5.91

A summary of option activity under the Company's equity incentive plans during the year ended December 31, 2021 was as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life (years)	Aggregate intrinsic value (1) (in thousands)
Outstanding as of January 1, 2021	3,049,875	\$ 1.10	8.86	\$ 4,467
Granted	2,967,648	8.39		
Exercised	(266,216)	1.03		
Forfeitures	(274,823)	4.08		
Outstanding as of December 31, 2021	5,476,484	4.90	8.64	39,325
Vested and expected to vest as of December 31, 2021	5,476,484	4.90	8.64	39,325
Exercisable as of December 31, 2021	1,324,664	0.93	7.83	13,780

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money as of December 31, 2021.

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2021 and 2020 was \$5.71 and \$1.05, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2021 and 2020 was \$1.8 million and \$0.4 million, respectively.

As of December 31, 2021, there was \$14.7 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.8 years.

### Restricted stock

In 2017, the Company issued 1,985,295 shares of restricted common stock to certain scientific founders, having a fair value of \$0.8 million, and subject to vesting over a period of 4 years.

If the holders of restricted common stock cease to have a business relationship with the Company prior to the vesting of such shares, the Company may reacquire any unvested shares of common stock held by these individuals for the original purchase price, and in certain instances for no consideration. The unvested shares of restricted common stock are not considered outstanding shares for accounting purposes until the shares vest.

As the restricted stock was fully vested in 2020, there was no remaining unrecognized stock-based compensation expense related to restricted stock as of December 31, 2021.

### 15. Net loss per share attributable to common stockholders

For periods in which the Company reports a net loss attributable to common stockholders, potentially dilutive securities have been excluded from the computation of diluted net loss per share as their effects would be anti-dilutive. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands except share and per share amounts):

	Year ended December 31,	
	2021	2020
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (68,280)	\$ (29,447)
<b>Denominator:</b>		
Weighted average number of common stock, basic and diluted	22,404,058	3,906,168
Net loss per common stock attributable to common stockholders, basic and diluted	<u>\$ (3.05)</u>	<u>\$ (7.54)</u>

The Company excluded the following potential common stock, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Year ended December 31,	
	2021	2020
Redeemable convertible preferred stock	—	23,605,211
Outstanding options to purchase common stock	5,476,484	3,049,875
Warrants	—	92,647
Total	<u>5,476,484</u>	<u>26,747,733</u>

### 16. Income taxes

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended December 31,	
	2021	2020
U.S. federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	7.6	7.7
Research and development tax credits	3.0	2.8
Nondeductible/ nontaxable permanent items	(0.9)	(0.5)
Change in valuation allowance	(30.8)	(30.8)
Other	0.1	(0.2)
Effective income tax rate%	<u>0%</u>	<u>0%</u>

The components of the Company's deferred taxes are as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 34,194	\$ 17,320
Research and development credit carryforwards	5,638	2,424
Accrued expenses	879	539
Stock-based compensation	528	9
Intangibles	152	167
Total deferred tax assets	41,391	20,459
Less: valuation allowance	(41,203)	(20,217)
Deferred tax assets, net	188	242
Deferred tax liabilities:		
Depreciation	(182)	(242)
Unrealized gain/loss	(6)	—
Total deferred tax liabilities	(188)	(242)
Net deferred taxes	\$ —	\$ —

The Company had no income tax expense due to the operating loss incurred for the years ended December 31, 2021 and 2020. Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's net deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets. As a result, the Company has recorded a full valuation allowance as of December 31, 2021 and 2020. The valuation allowance increased by \$21.0 million in 2021, due to the increase in deferred tax assets, primarily resulting from the net operating loss carryforwards, research and development tax credits, stock based compensation expense and deductible accrued expenses.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards, which could be used annually to offset future taxable income. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and because there could be additional changes in control in the future. As a result, the Company is not able to estimate the effect of the change in control, if any, on the Company's ability to utilize net operating loss and research and development credit carryforwards in the future.

As of December 31, 2021, the Company had \$125.8 million of federal and \$123.0 million of state net operating loss carryforwards. If not utilized, both the federal and state net operating loss carryforwards have components that begin to expire starting in 2036. Of the \$125.8 million federal net operating loss carryforwards, \$120.3 million of net operating loss generated from 2018 to 2021 will not expire. Additionally, as of December 31, 2021, the Company had \$3.4 million of federal and \$2.8 million of Massachusetts tax credits that expire starting in 2036 and 2031, respectively.

As of December 31, 2020, the Company had \$63.6 million of federal and \$62.6 million of state net operating loss carryforwards. If not utilized, both the federal and state net operating loss carryforwards have components that begin to expire starting in 2036. Of the \$63.6 million federal net operating loss carryforwards, \$58.1 million of net operating loss generated from 2018 to 2020 will not expire. Additionally, as of December 31, 2020, the Company had \$1.4 million of federal and \$1.3 million of Massachusetts tax credits that expire starting in 2036 and 2031, respectively.

As of December 31, 2021 and 2020, the Company had no uncertain tax positions. The Company will recognize both interest and penalties associated with unrecognized tax benefits as a component of income tax expense. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception.



The Company filed income tax returns in the United States and the Commonwealth of Massachusetts in all tax years since inception. The tax years 2020 and 2019 remain open to examination by these jurisdictions, as carryforward attributes generated in past years may be adjusted in a future period. The Company is not currently under examination by the Internal Revenue Service or any other taxing authority for these years.

## **17. Related party transactions**

The majority ownership of the Company is held by Flagship, in which it holds shares representing approximately 54% of the Company's outstanding voting stock as of December 31, 2021. Flagship historically provided management services (accounting, human resources, information technology, legal and consultation) to the Company. Flagship is also reimbursed for certain expenses, including insurance and benefits, partner and related fees, and software licenses incurred on the Company's behalf. For the years ended December 31, 2021 and 2020, the Company incurred \$1.0 million and \$0.9 million, respectively, primarily for the management services fees and reimbursable expenses. These expenses are recorded as related party expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2021, there was an immaterial amount of outstanding payment due to Flagship; as of December 31, 2020, the Company did not have any outstanding payments due to Flagship.

In September 2020, the Company sublet the entire space of its 325 Vassar Street facility, approximately 19,404 square feet, to LARONDE, Inc. ("LARONDE", formerly known as VL50, Inc.), which is an affiliate of Flagship. The sublease term will expire at the end of the Company's lease agreement with the landlord in September 2024. The rental rate for the sublease arrangement is equal to the Company's rental obligation per the agreement with BMR-325 Vassar Street LLC, reduced by the sublease income received from Cygnal Therapeutics, Inc ("Cygnal"), approximating \$1.3 million per year. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management. Under the sublease agreement, the Company received rental income of \$2.0 million and 0.6 million, which was recorded as a reduction of rental expenses, during the years ended December 31, 2021 and 2020, respectively. Such rental income was reflected as a reduction of related party expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2021 and 2020, there was no outstanding receivable due from LARONDE.

In September 2019, the Company sublet approximately 1,445 square feet of its 325 Vassar Street facility to Cygnal, which is an affiliate of Flagship, for two years. The lease term can continue on a month-to-month basis until advanced notice is provided to the Company. Upon the lease term ended in September 2021, Cygnal elected to continue leasing the space until December 2022. The rental rate for the sublease arrangement is equal to the Company's rental obligation per the agreement with BMR-325 Vassar Street LLC, approximating \$0.1 million per year. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management. Under the sublease agreement, the Company received rental income of \$0.2 million and \$0.1 million, which was recorded as reduction of rental expenses, during the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, there was no outstanding receivable due from Cygnal.

Refer to other related party transactions as described in Note 9, *Commitments and contingencies*, Note 10, *License agreements* and Note 11, *Collaboration agreement*.

## **18. Employee benefits**

In 2018, the Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company is not required to make and has not made any matching contributions to the 401(k) Plan to date.

## DESCRIPTION OF CAPITAL STOCK

As of December 31, 2021, Omega Therapeutics, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). References herein to “we,” “us,” “our” and the “Company” refer to Omega Therapeutics, Inc. and not to any of its subsidiaries.

### Capital Structure

The following description of our capital stock and certain provisions of our restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to our restated certificate of incorporation and our amended and restated bylaws, each of which has been publicly filed with the Securities and Exchange Commission (“SEC”).

#### *General*

Our authorized capital stock consists of 210,000,000 shares, all with a par value of \$0.001 per share, of which:

- 200,000,000 shares are designated as common stock; and
- 10,000,000 shares are designated as preferred stock.

#### *Common Stock*

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation. See below under “—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions.” Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

#### *Preferred Stock*

Under the terms of our restated certificate of incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could

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have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock.

### **Registration Rights**

The second amended and restated investors' rights agreement by and among us and certain of our stockholders (the "Investors' Rights Agreement") grants the parties thereto the following rights with respect to the registration of "Registrable Securities" held by them for public resale under the Securities Act of 1933, as amended (the "Securities Act") until such shares can otherwise be sold without restriction under Rule 144 of the Securities Act, or until the rights otherwise terminate pursuant to the terms of the Investors' Rights Agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

#### ***Form S-1 Registration Rights***

If at any time the holders of registrable securities request in writing that we effect a registration with respect to all or part of such registrable securities then outstanding and having an anticipated aggregate offering price that would exceed \$10,000,000, net of expenses, we may be required to register their shares. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

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

If we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

#### ***Form S-3 Registration Rights***

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of at least 30% of the registrable securities request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least \$5,000,000, we will be required to effect such registration; provided, however, that we will not be required to effect such a registration if, within any twelve month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

#### ***Expenses and Indemnification***

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration, filing and qualification fees, printers' and accounting fees, fees and disbursements of our counsel and reasonable fees and disbursements of a counsel for the selling securityholders. Additionally, we have agreed to indemnify selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement or alleged untrue statement of a material fact contained in any registration statement, an omission or alleged omission to state a material fact required to be stated in any registration statement, or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

#### ***Termination of Registration Rights***

The registration rights terminate upon the earlier of (i) July 29, 2026, (ii) immediately before the closing of a deemed liquidation event, as defined in our current certificate of incorporation and (iii) at such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of a holders' shares without

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limitation during a three-month period without registration, or if a holder is an affiliate of the Company, at such time as such holder is no longer an affiliate of the Company.

### **Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws**

Some provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

#### ***Undesignated Preferred Stock***

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

#### ***Stockholder Meetings***

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

#### ***Requirements for Advance Notification of Stockholder Nominations and Proposals***

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

#### ***Elimination of Stockholder Action by Written Consent***

Our restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

#### ***Staggered Board***

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

#### ***Removal of Directors***

Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

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### ***Stockholders Not Entitled to Cumulative Voting***

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

### ***Delaware Anti-Takeover Statute***

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

### ***Choice of Forum***

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act, or to any claim for which the federal courts have exclusive jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, Exchange Act, or the rules and regulations thereunder. Our restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. These provisions may have the effect of discouraging lawsuits against our directors, officers, employees, and agents as it may limit any stockholder’s ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees, or agents and result in increased costs for investors to bring a claim. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

### ***Amendment of Charter Provisions***

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon. The provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and

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management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

**Listing**

Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol “OMGA.”

**Transfer Agent and Registrar**

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

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## Employment Agreement

This Employment Agreement (this “Agreement”), dated as of December 12, 2021, is made by and between Omega Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the “Company”), and Yan Moore (“Executive”) (collectively referred to herein as the “Parties” or individually referred to as a “Party”). This Agreement shall be effective as of the date of execution by the Parties (the “Effective Date”).

### RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive commencing on or about January 3<sup>rd</sup>, 2022 (the “Start Date”) and thereafter by entering into this Agreement.
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

### AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

#### **1. Employment.**

(a) General. Effective on the Start Date, the Company shall employ Executive, and Executive shall be employed by the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Start Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Chief Medical Officer of the Company, with such responsibilities, duties and authority normally associated with such position and as may from time to time be assigned to Executive by the President and Chief Executive Officer of the Company (the “CEO”). Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the CEO, provided that Executive shall be permitted to (i) manage Executive’s personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive’s performance

of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case, as amended from time to time, and as delivered or made available to Executive (each, a "Policy").

## **2. Compensation and Related Matters.**

(a) **Annual Base Salary.** During the Term, Executive shall receive a base salary at a rate of \$505,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board") (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) **Annual Cash Bonus Opportunity.** During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Annual Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) **Benefits.** During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company, subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) **Vacation.** During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) **Business Expenses.** During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) **Key Person Insurance.** At any time during the Term, the Company shall have the right (but not the obligation) to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

(g) **Sign-On Bonus.** Executive shall be eligible to receive a sign-on bonus in the total amount of \$458,000, payable as follows: (i) \$208,000 (the "First Installment") will be paid on the first scheduled payroll date following the Start Date; and (ii) up to \$250,000 (the "Second Installment") will be paid on or about May 31st, 2022. Executive acknowledges that the First Installment is intended to compensate the Executive for the amount of annual cash bonus the Executive would have otherwise earned for fiscal

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year 2021 from his prior employer had he remained employed (the “Lost Bonus”), and that the Second Installment is intended to compensate the Executive for the value of the restricted stock units issued by his prior employer that were forfeited as a result of his termination of employment with his prior employer (the “Lost RSUs”). However, in the event that the Executive’s prior employer pays or delivers to Executive all or a portion of the value of the Lost Bonus or Lost RSUs (each, a “Prior Employer Payment”), then, notwithstanding anything herein to the contrary, the Company’s obligation to pay the First Installment and/or the Second Installment, as applicable, shall be reduced (including to zero, if applicable) by the Prior Employer Payment, and to the extent the First Installment or Second Installment, as applicable, was already paid by the Company, the Executive shall pay an amount equal to the Prior Employer Payment to the Company as soon as practicable after such receipt. The amount of any reduction or repayment obligation under the immediately preceding sentence will be determined by the Company in its good faith discretion. In addition, and notwithstanding the foregoing, if the Executive’s employment is terminated by the Company for Cause or by Executive other than for Good Reason (as defined below), in either case within eighteen months of the payment of each of the First Installment or Second Installment, Executive will repay to the Company the full amount of the First Installment and/or the Second Installment, as applicable. The Company will be entitled (but not required) to deduct the amount of any such repayment obligations pursuant to this Section 2(g) from any amounts otherwise payable to Executive by the Company or any of its affiliates.

(h) Sign-On Equity Award. Subject to the approval of the Board, Executive will be granted an option to purchase 477,715 shares (1%) of common stock of the Company with an exercise price per share equal to the closing price per share of the Company’s common stock on the date of grant or the last trading day preceding the date of grant if the date of grant is not a trading day (the “Option”). Subject to Executive’s continued employment by the Company, the Option shall vest over a four-year period, with 25% of the underlying shares vesting on the first anniversary of the Start Date and 6.25% of the underlying shares vesting upon the Executive’s completion of each three full months of employment thereafter. The Option will be subject to the terms of the Company’s incentive award plan under which it is granted and the award agreement evidencing the award.

### **3.Termination.**

Executive’s employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

- (a) Circumstances.
    - (i) *Death*. Executive’s employment hereunder shall terminate upon Executive’s death.
    - (ii) *Disability*. If Executive has incurred a Disability, as defined below, the Company may terminate Executive’s employment, provided that such termination would not violate any federal or state disability, paid family leave or other applicable law.
    - (iii) *Termination for Cause*. The Company may terminate Executive’s employment for Cause, as defined below.
    - (iv) *Termination without Cause*. The Company may terminate Executive’s employment without Cause.
    - (v) *Resignation from the Company with Good Reason*. Executive may resign Executive’s employment with the Company with Good Reason, as defined below.
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(vi) Resignation from the Company without Good Reason. Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to Section 3(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided, however,* that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

#### **4. Severance Payments.**

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation with Good Reason, then except as otherwise provided under Section 4(c) and subject to Executive signing on or before the 21st day following Executive's Separation

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from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the “Release”) and Executive’s continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 0.75 times the Annual Base Salary, payable in the form of salary continuation in regular installments over the 9 month period following the date of Executive’s Separation from Service (the “Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company’s fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company’s group medical, dental or vision plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“COBRA”), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive’s covered dependents under such plans, less the amount Executive would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on the Date of Termination, during the period commencing on Executive’s Separation from Service and ending upon the earliest of (A) the last day of the Severance Period, (B) the date that Executive and/or Executive’s covered dependents become no longer eligible for COBRA or (C) the date Executive becomes eligible to receive medical, dental or vision coverage, as applicable, from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility) (the “COBRA Continuation Period”). Notwithstanding the foregoing, if the Company determines it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive’s and Executive’s covered dependents’ group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), less the amount Executive would have had to pay to receive such group health coverage as an active employee for Executive and his or her covered dependents based on the cost sharing levels in effect on the Date of Termination, which payments shall for the remainder of the COBRA Continuation Period.

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, in either case, on or within twelve (12) months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive’s Separation from Service, and not revoking, the Release and Executive’s continued compliance with Section 5, Executive shall receive, in addition to the payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in equal installments over the 12 month period following the date of Executive’s Separation from Service (the “CIC Severance Period”) in accordance with the Company’s normal payroll practices;

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- (ii) the payment set forth in Section 4(b)(ii);
  - (iii) the benefits set forth in Section 4(b)(iii), provided that for this purpose, the “Severance Period” will mean the CIC Severance Period;
  - (iv) an amount in cash equal to 1.0 times the Target Annual Bonus, payable in a lump sum on the Company’s first ordinary payroll date that occurs after the Date of Termination; and
  - (v) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on continued employment or service shall immediately become 100% vested, with any other equity or equity-based awards being governed by the terms of the applicable award agreement.
- (d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive’s employment and the termination of the Term.

**5. Restrictive Covenants.** As a condition to the effectiveness of this Agreement, Executive will have executed and delivered to the Company no later than contemporaneously herewith the Employee Non-Solicitation, Confidentiality and Assignment Agreement and Employee Non-Competition Agreement, attached as Exhibit B (together, the “Restrictive Covenant Agreement”). Executive agrees to abide by the terms of the Restrictive Covenant Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement will survive the termination of Executive’s employment and the termination of the Term for the periods set forth in the Restrictive Covenant Agreement.

#### **6. Assignment and Successors.**

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive’s rights or obligations may be assigned or transferred by Executive, other than Executive’s rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive’s death by giving written notice thereof to the Company.

#### **7. Certain Definitions.**

- (a) Cause. The Company shall have “Cause” to terminate Executive’s employment hereunder upon:
    - (i) The CEO’s reasonable, good faith determination that Executive has refused to (A) substantially perform the duties associated with Executive’s position with the Company or (B) carry out the reasonable and lawful instructions of the CEO concerning duties or actions consistent with the Executive’s position with the Company;
    - (ii) Executive’s breach of a material provision of this Agreement that, to the extent capable
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of cure, has remained uncured for a period of thirty (30) days following written notice from the Company;

(iii) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(iv) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(v) Executive's commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the Omega Therapeutics, Inc. 2021 Incentive Award Plan, as in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) Disability. "Disability" shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company's employees, "disability" as defined in such long-term disability plan for the purpose of determining a participant's eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, "Disability" shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, "Disability" shall mean Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be with "Good Reason" if Executive resigns within ninety (90) days after any of the following events, unless Executive consents in writing to the applicable event: (i) a reduction in Executive's Annual Base Salary or Target Annual Bonus, (ii) a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or position with the Company, (iii) the relocation of Executive's primary office to a location more than twenty-five (25) miles from the Executive's primary office as of the date of this Agreement or (iv) the Company's breach of a material provision of this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until: (a) Executive has provided the Company, within sixty (60) days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable

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facts and circumstances underlying such finding of Good Reason; (b) the Company has had an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (c) the Company shall have failed to so cure within such period.

## **8. Parachute Payments.**

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4 hereof, being hereinafter referred to as the “Total Payments”), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro rata basis of any cash severance payments that are exempt from Section 409A of the Code (“Section 409A”), (ii) reduction on a pro rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the “Independent Advisors”). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a “parachute payment” within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the “base amount” (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

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## **9. Miscellaneous Provisions.**

(a) **Governing Law.** This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) **Validity.** The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) **Notices.** Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, to the CEO of the Company at the Company's headquarters,
- (ii) If to Executive, to the last address that the Company has in its personnel records for Executive, or
- (iii) At any other address as any Party shall have specified by notice in writing to the other Party.

(d) **Counterparts.** This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) **Entire Agreement.** The terms of this Agreement, and the Restrictive Covenant Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including any prior employment offer letter or employment agreement between Executive and the Company. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) **Amendments; Waivers.** This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) **Construction.** This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to

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paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(h) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney’s fees and expenses; provided that the arbitrator may assess the prevailing Party’s fees and costs against the non-prevailing Party as part of the arbitrator’s award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; provided, however, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or the Restrictive Covenant Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association (“AAA”) shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

(i) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(j) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

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(k) Section 409A.

(i) *General.* The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service.* Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 5 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

**10.Executive Acknowledgement.**

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company

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other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

*[Signature Page Follows]*

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IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

**OMEGA THERAPEUTICS, INC.**

By: /s/ Mahesh Karande  
Name: Mahesh Karande  
Title: President and CEO

**EXECUTIVE**

/s/ Yan Moore  
Yan Moore, MD

*[Signature Page to Employment Agreement]*

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## EXHIBIT A

### Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between \_\_\_\_\_ ("Executive") and Omega Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of \_\_\_\_\_, 2021 (the "Employment Agreement") and that certain Employee Non-Solicitation, Confidentiality and Assignment Agreement (the "Non-Disclosure Agreement") and Employee Non-Competition Agreement, dated as of \_\_\_\_\_, 2021 (the "Non-Competition Agreement," and together, the "Restrictive Covenant Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective \_\_\_\_\_, 20\_\_, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. **Severance Payments and Benefits; Salary and Benefits.** The Company agrees to provide Executive with the severance payments and benefits described in Section [4(b)/4(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. **Release of Claims.** Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the

Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

- (a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;
- (b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;
- (c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;
- (d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;
- (e) any and all claims for violation of the federal or any state constitution;
- (f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;
- (g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;
- (h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and
- (i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or

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regulation and any right to receive an award for information provided thereunder, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company for discrimination (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from the Company or any Releasee for any alleged discriminatory treatment), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law and any Retained Claims. This release further does not release claims for breach of Section 3(c) or Section 4 of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Proprietary Information (as defined in the Non-Disclosure Agreement), non-solicitation, cooperation, and return of property, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law, except that the Parties expressly agree to modify the Restrictive Covenant Agreement by removing Section 1, and each subpart thereto, of the Non-Competition Agreement, which shall be of no further force or effect upon the Effective Date (as defined below). Executive represents and warrants that Executive has complied with all provisions of the Restrictive Covenant Agreement at all times through the Effective Date.

(b) In consideration for the severance payments and benefits set forth in Section 1 of this Agreement, Executive agrees for a period of one year after the Effective Date (the "Non-Competition Restricted Period") to not, directly or indirectly, on Executive's own behalf or for the benefit of any other

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individual or entity other than the Company: (i) operate, conduct, or engage in, or prepare to operate, conduct, or engage in the Business (as defined below); (ii) own, finance, or invest in (except as the holder of not more than one percent of the outstanding stock of a publicly-held company) any Business; or (iii) participate in, render services to, or assist any person or entity that engages in or is preparing to engage in the Business in any capacity (whether as an employee, consultant, contractor, partner, officer, director, or otherwise) (x) which involves the same or similar types of services Executive performed for the Company at any time during the last two years of Executive's employment with the Company or (y) in which Executive could reasonably be expected to use or disclose Proprietary Information, in each case (i), (ii) or (iii) in the Restricted Territory (as defined below). Without limiting the Company's ability to seek other remedies available in law or equity, if Executive violates this Section 4(b), the Non-Competition Restricted Period shall be extended by one day for each day that Executive is in violation of such provisions, up to a maximum extension equal to the length of the Non-Competition Restricted Period, so as to give the Company the full benefit of the bargained-for length of forbearance.

(c) Executive's continued compliance with the terms of the Restrictive Covenant Agreement (as modified in Section 4(a) above) and the noncompetition obligations set forth in Section 4(b) above (collectively, the "Restrictive Covenants") is a material condition to receipt of the severance payments and benefits set forth in Section 1 of this Agreement. In the event Executive breaches any part of such Restrictive Covenants, then, in addition to any remedies and enforcement mechanisms set forth in the Non-Competition Agreement, the Employment Agreement and this Agreement, and any other remedies available to the Company (including equitable and injunctive remedies), Executive shall forfeit any additional consideration owing and shall be obligated to promptly return to the Company (within fifteen (15) business days of any breach) the full gross amount of all severance payments and benefits provided.

(d) If any provision of the Restrictive Covenants shall be determined to be unenforceable by any court of competent jurisdiction or arbitrator by reason of its extending for too great a period of time or over too large a geographic area or over too great a range of activities, it shall be interpreted to extend only over the maximum period of time, geographic area or range of activities as to which it may be enforceable.

(e) As used in this Agreement:

(i) The term "Business" means any business or part thereof that develops, manufactures, markets, licenses, sells or provides any product or service that competes with any product or service developed, manufactured, marketed, licensed, sold or provided, or planned to be developed, manufactured, marketed, licensed, sold or provided, by the Company, in each case at any time during Executive's employment or engagement with the Company.

(ii) The term "Restricted Territory" means each city, county, state, territory and country in which (i) Executive provided services or had a material presence or influence at any time during the last two years of Executive's employment or engagement with the Company or (ii) the Company is engaged in or has plans to engage in the Business as of the termination of Executive's employment or engagement with the Company.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

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6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c), and 9(h) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective on the day immediately following the seventh business day after Executive signed this Agreement (the "Effective Date"). For the avoidance of doubt, if Executive revokes this Agreement as provided herein, the Parties' modification to the Non-Competition Agreement set forth in Section 4(a) above shall be void and of no effect and, unless the Company has elected or elects in writing to expressly waive Executive's noncompetition obligations set forth in Section 1(a) of the Non-Competition Agreement as provided in Section 3 of the Non-Competition Agreement, the Non-Competition Agreement, including without limitation Section 1 of the Non-Competition Agreement, shall remain in full force and effect.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

**EXECUTIVE**

Dated:

\_\_\_\_\_

**OMEGA THERAPEUTICS, INC.**

Dated:

By: \_\_\_\_\_

Name:

Title:

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**EXHIBIT B**

**Restrictive Covenant Agreement**

[attached]

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CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the “Agreement”), made this 7<sup>th</sup> day of November, 2016 (the “Effective Date”) is entered into by VL42, Inc., a Delaware corporation with offices at 55 Cambridge Parkway, 8th Floor, Cambridge, MA 02142 (the “Company”), and Richard A. Young, Ph.D., (the “Consultant”) (each herein referred to individually as a “Party,” or collectively as the “Parties”).

INTRODUCTION

The Company is engaged or plans to engage in the research, development and/or commercialization of biologics affecting chromatin structure and/or insulator activity (the “Field”). The Consultant has extensive experience in the Field, and the Company desires to retain the services of the Consultant and the Consultant desires to perform certain services for the Company. In consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the Parties hereto, the Parties agree as follows:

1. Services. The Consultant agrees to perform such consulting, advisory and related services to and for the Company as may be reasonably requested from time to time by the Company, including without limitation, consulting, advisory and related services to the Company with respect to matters related to the Field. The Consultant agrees to devote at most 12 days per year to the performance of such services. Without limiting the additional terms and conditions of Section 7 below, during the Consultation Period (as defined below), the Consultant shall not knowingly engage in any activity that has a conflict of interest with the Company, including without limitation any competitive employment, business, or other activity, and he shall not knowingly assist any other person or organization that competes or intends to compete with the Company. The Company acknowledges that Consultant has consulting obligations to those companies set forth on Annex 1 and does not view these as constituting a conflict of interest with the Company. The Company also acknowledges that the Consultant is a Member of the Whitehead Institute for Biomedical Research (“WIBR”) and faculty member in the Department of Biology of the Massachusetts Institute of Technology (“MIT”) and that no activity carried out by the Consultant in his capacity as a Member of WIBR will be considered a conflict of interest to Company. The Whitehead Institute Uniform Consulting Agreement Provisions (“Standard Provisions”) are attached hereto as Exhibit A and are incorporated herein by reference. The Parties agree that the Standard Provisions are an integral part of this Agreement and this Agreement shall have no force or effect unless the Standard Provisions are signed by both Parties. The Parties agree that in the event of any conflict between this Agreement and the Standard Provisions, the Standard Provisions shall govern and prevail.

2. Term. The initial term of this Agreement (the “Initial Term”) shall commence on the Effective Date and shall continue until the first anniversary of the Effective Date, unless sooner terminated in accordance with the provisions of Section 4. At the expiration of the Initial Term,

this Agreement will automatically renew for successive one-year periods and terminating on the fourth anniversary of the Effective Date, unless sooner terminated in accordance with the provisions of Section 4 (the term of effectiveness of this Agreement being referred to herein as the "Consultation Period").

3. Compensation.

3.1 Consulting Fees. The Company has granted to the Founder shares of common stock of the Company, the continued vesting of which is subject to the Consultant's provision of services to the Company pursuant to this Agreement.

3.2 Fees. From the Effective Date until the Qualified Financing Date (as defined below), the Company shall pay to the Consultant consulting fees at a rate of \$25,000 per year, payable in arrears in equal quarterly installments. From and after the First Qualified Financing Date until the Second Qualified Financing Date, the Company shall pay to the Consultant consulting fees at a rate of \$75,000 per year, payable in arrears in equal quarterly installments. Payment for any partial quarter shall be prorated. For purposes of this Agreement, "First Qualified Financing Date" shall mean the first date on which the Company receives aggregate gross proceeds of at least \$10,000,000 from the sale to third parties of shares of its stock. From and after the Second Qualified Financing Date, the Company shall pay to the Consultant consulting fees at a rate of \$120,000 per year, payable in arrears in equal quarterly installments. Payment for any partial quarter shall be prorated. For purposes of this Agreement, "Second Qualified Financing Date" shall mean the first date on which the Company receives aggregate gross proceeds of at least \$20,000,000 from the sale to third parties of shares of its stock.

3.3 Reimbursement of Expenses. The Company shall reimburse the Consultant for all reasonable and necessary documented out of pocket expenses incurred or paid by the Consultant in connection with, or related to, the performance of his services under this Agreement with the prior written approval of the Company. The Consultant shall submit to the Company itemized monthly statements, in a form satisfactory to the Company, of such expenses incurred in the previous month. The Company shall pay to the Consultant amounts shown on each such statement within thirty (30) days after receipt thereof.

3.4 Benefits. The Consultant shall not be entitled to any benefits, coverages or privileges, including, without limitation, social security, unemployment, medical or pension payments, made available to employees of the Company.

4. Termination. This Agreement may be terminated at any time during the Consultation Period in the following manner: (a) by either the Company or the Consultant upon not less than thirty (30) days prior written notice to the other Party, provided that the Company may in its discretion elect to terminate this Agreement immediately (i) if the Consultant delivers such written notice of termination or (ii) if the Company delivers such notice of termination and pays the Consultant within 15 days after such termination a lump-sum amount equal to the portion of the consulting fees payable hereunder that the Consultant would have earned during the thirty (30) day notice period; (b) by the non-breaching Party, upon twenty-four (24) hours prior written notice to the breaching Party if one Party has materially breached this Agreement and, except as

set forth in the last sentence of this Section 4, the breaching Party fails to cure such breach within thirty (30) days of such written notice; or (c) at any time upon the mutual written consent of the Parties hereto. In the event of such termination, the Consultant shall be entitled to payment for services performed and expenses paid or incurred prior to the effective date of termination, subject to the limitation on reimbursement of expenses set forth in Section 3.3. Such payments shall constitute full settlement of any and all claims of the Consultant of every description against the Company. Notwithstanding the foregoing, the Company may terminate the Consultation Period, effective immediately upon receipt of written notice, if the Consultant breaches or threatens to breach any provision of Section 6 or Section 7. The provisions of Sections 5, 6, 7, 8, 10 through 18 shall survive any termination of this Agreement.

5. Cooperation. The Consultant shall use his best efforts in the performance of his obligations under this Agreement. The Company shall provide such access to its information and property as may be reasonably required in order to permit the Consultant to perform his obligations hereunder. The Consultant shall cooperate with the Company's personnel, shall not interfere with the conduct of the Company's business and shall observe all rules, regulations and security requirements of the Company concerning the safety of persons and property.

6. Inventions and Proprietary Information.

6.1 Inventions.

(a) All inventions, discoveries, computer programs, data, technology, designs, innovations and improvements (whether or not patentable and whether or not copyrightable) which are made, conceived, reduced to practice, created, written, designed or developed by the Consultant, solely or jointly with others and whether during normal business hours or otherwise, (i) during the Consultation Period that result from the performance of Consultant's services and if related to the business of the Company or (ii) during or after the Consultation Period if resulting or directly derived from Proprietary Information (as defined below), ("Inventions") shall be the sole property of the Company. The Consultant hereby assigns to the Company all Inventions and any and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefor, in the United States and elsewhere and appoints any officer of the Company as his duly authorized attorney to execute, file, prosecute and protect the same before any government agency, court or authority. Upon the request of the Company and at the Company's expense, the Consultant shall execute such further assignments, documents and other instruments as may be necessary or desirable to fully and completely assign all Inventions to the Company and to assist the Company in applying for, obtaining and enforcing patents or copyrights or other rights in the United States and in any foreign country with respect to any Invention. The Consultant also hereby waives all claims to moral rights in any Inventions.

(b) The Consultant shall promptly disclose to the Company all Inventions and will maintain adequate and current written records (in the form of notes, sketches, drawings and as may be specified by the Company) to document the conception and/or first actual reduction to practice of any Invention. Such written records shall be available to and remain the sole property of the Company at all times.

## 6.2 Proprietary Information.

(a) The Consultant acknowledges that his relationship with the Company is one of high trust and confidence and that in the course of his service to the Company he will have access to and contact with Proprietary Information. The Consultant agrees that he will not, during the Consultation Period or at any time thereafter, disclose to others, or use for his benefit or the benefit of others, any Proprietary Information or Invention.

(b) For purposes of this Agreement, Proprietary Information shall mean, by way of illustration and not limitation, all information (whether or not patentable and whether or not copyrightable) owned, possessed or used by the Company, including, without limitation, any Invention, formula, vendor information, customer information, apparatus, equipment, process, research, report, technical data, know-how, computer program, software, software documentation, hardware design, technology, marketing or business plan, forecast, unpublished financial statement, budget, license, price, cost and employee list that is communicated to, learned of, developed or otherwise acquired by the Consultant in the course of his service as a consultant to the Company.

(c) The Consultant's obligations under this Section 6.2 shall not apply to any information (none of which shall be deemed Proprietary Information) that (i) is or becomes known to the general public under circumstances involving no breach by the Consultant of the terms of this Section 6.2, (ii) is generally disclosed to third parties by the Company without restriction on such third parties, (iii) is approved for release by written authorization of the Board of Directors of the Company, (iv) is independently developed by or for Consultant without use of Proprietary Information, or (v) Consultant is obligated to produce pursuant to an order of a court of competent jurisdiction or a valid administrative or Congressional subpoena, provided that the Consultant promptly notify Company and cooperate reasonably with Company's efforts to contest or limit the scope of such order. The Consultant's obligations hereunder shall survive for a period of five (5) years from the expiration or earlier termination of this Agreement.

(d) Upon termination of this Agreement or at any other time upon request by the Company, the Consultant shall promptly deliver to the Company all records, files, memoranda, notes, designs, data, reports, price lists, customer lists, drawings, plans, computer programs, software, software documentation, sketches, laboratory and research notebooks and other documents (and all copies or reproductions of such materials) relating to the business of the Company.

(e) The Consultant represents that his retention as a consultant with the Company and his performance under this Agreement does not, and shall not, breach any agreement that obligates him to keep in confidence any trade secrets or confidential or proprietary information of his or of any other party or to refrain from competing, directly or indirectly, with the business of any other party or otherwise conflict with any of his agreements or obligations to any other party. The Consultant shall not disclose to the Company any trade secrets or confidential or proprietary information of any other party.

(f) The Consultant acknowledges that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, that impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. The Consultant agrees to be bound by all such obligations and restrictions that are known to him and to take all action necessary to discharge the obligations of the Company under such agreements.

6.3 Defend Trade Secrets Act Notice of Immunity Rights. Consultant acknowledges that the Company has provided him with the following notice of immunity rights in compliance with the requirements of the Defend Trade Secrets Act: (a) Consultant shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Proprietary Information that is made in confidence to a Federal, State, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, (b) Consultant shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Proprietary Information that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal and (c) Consultant files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Consultant may disclose the Proprietary Information to his attorney and use the Proprietary Information in the court proceeding, if Consultant files any document containing the Proprietary Information under seal, and does not disclose the Proprietary Information, except pursuant to court order.

7. Non-Competition and Non-Solicitation.

7.1 Restrictions. During the term of this Agreement and for a period of one year after termination of this Agreement, the Consultant will not directly or indirectly:

(a) Engage or assist others in engaging in any business or enterprise competing with the Company in the Field (whether as owner, partner, officer, director, employee, consultant, investor, lender or otherwise, except as the holder of not more than 1% of the outstanding stock of a publicly-held company), including but not limited to any business or enterprise that develops, manufactures, markets, licenses, sells or provides any product or service that competes with any product or service developed, manufactured, marketed, licensed, sold or provided, or planned to be developed, manufactured, marketed, licensed, sold or provided, by the Company in the Field while the Consultant was employed by the Company;

(b) Either alone or in association with others, divert or take away, or attempt to divert or take away, the business or patronage of any of the clients, customers, or business partners of the Company which were contacted, solicited, or served by the Company during the 12-month period prior to the termination or cessation of the Consultant's services with the Company; or

(c) Either alone or in association with others (i) solicit, induce or attempt to induce, any employee or independent contractor of the Company to terminate his or her employment or other engagement with the Company, or (ii) hire, or recruit or attempt to hire, or

engage or attempt to engage as an independent contractor, any person who was employed or otherwise engaged by the Company at any time during the term of the Consultant's services with the Company; provided, that this clause (ii) shall not apply to the recruitment or hiring or other engagement of any individual whose employment or other engagement with the Company has been terminated for a period of six months or longer.

7.2 Extension. If the Consultant violates the provisions of Section 7.1, the Consultant shall continue to be bound by the restrictions set forth in such paragraph until a period of one (1) year has expired without any violation of such provisions.

7.3 Company's Business. For purposes of this Agreement, the "Company's business" shall mean the any lawful act or activity relating to the Field.

8. Remedies. The Consultant acknowledges that any breach of the provisions of Section 6 or Section 7 shall result in serious and irreparable injury to the Company for which the Company cannot be adequately compensated by monetary damages alone. The Consultant agrees, therefore, that, in addition to any other remedy it may have, the Company shall be entitled to enforce the specific performance of this Agreement by the Consultant and to seek both temporary and permanent injunctive relief (to the extent permitted by law) without the necessity of proving actual damages.

9. Other Agreements. The Consultant hereby represents that, except as the Consultant has disclosed in writing to the Company (which writing shall redact, however, any elements that Consultant is not lawfully permitted to disclose), the Consultant is not bound by the terms of any agreement with any third party (excluding for this purpose any academic and research institutions or not-for-profit organizations) to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of the Consultant's relationship with the Company, to refrain from competing, directly or indirectly, with the business of such third party or to refrain from soliciting employees, customers or suppliers of such third party. The Consultant agrees to furnish the Company with a copy of any such agreement upon request.

10. Independent Contractor Status. The Consultant shall perform all services under this Agreement as an "independent contractor" and not as an employee or agent of the Company. The Consultant is not authorized to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, the Company or to bind the Company in any manner.

11. Notices. All notices required or permitted under this Agreement shall be in writing and shall be deemed effective upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party at the address shown above, or at such other address or addresses as either party shall designate to the other in accordance with this Section 11.

12. Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

13. Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement.

14. Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Consultant.

15. Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the laws of the Commonwealth of Massachusetts without regard to conflict of law principles that would result in the application of any law other than the Commonwealth of Massachusetts.

16. Interpretation. If any restriction set forth in Section 1 or Section 7 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 of activities or geographic area as to which it may be enforceable.

17. Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to its assets or business, provided, however, that the obligations of the Consultant are personal and shall not be assigned by him.

18. Miscellaneous.

18.1 No delay or omission by the Company in exercising any right under this 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 or waiver of any right on any other occasion.

18.2 The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. In the event that any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

*[Remainder of page intentionally left blank]*



IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

VL42, INC.

By: /s/ David A. Berry  
David A. Berry, M.D., Ph.D., President

\_\_\_\_\_  
/s/ Richard A. Young  
Richard A. Young, Ph.D.  
Address:

[SIGNATURE PAGE TO FOUNDER CONSULTING AGREEMENT]

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## Exhibit A

### **WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH UNIFORM CONSULTING AGREEMENT**

#### **PROVISIONS**

1. The Whitehead Institute for Biomedical Research (“WHITEHEAD”) is a non-profit biomedical research institute having a business address of Nine Cambridge Center, Cambridge, Massachusetts 02142. These Uniform Consulting Agreement Provisions (the “Uniform Provisions”) are attached to an agreement (the “Agreement”) under which a Member of WHITEHEAD (the “Consultant”) has agreed to provide consulting services to the company named in the Agreement (the “Company”). The Consultant and the Company agree that the Agreement shall have no force or effect unless these Uniform Provisions are signed by both parties and attached to the Agreement. By signing the Uniform Provisions, the Consultant and the Company agree to abide by them, and also agree that if anything in the Agreement is inconsistent with the Uniform Provisions, the Uniform Provisions shall govern.
2. The Agreement shall disclose all compensation of whatever kind that is to be provided to the Consultant in connection with the consulting services. The Agreement shall disclose the time commitment for the consulting services, which may not exceed one day per week for all outside activities of the Member of WHITEHEAD.
3. The Consultant’s services for the Company shall consist only of the exchange of ideas and provision of advice; the Consultant shall not direct or conduct research for or on behalf of the Company.
4. The Company acknowledges that the Consultant is a Member of WHITEHEAD and is subject to WHITEHEAD’s policies, including policies concerning consulting, conflicts of interest, and intellectual property. In accordance with WHITEHEAD policy, the Consultant may disclose to the Company any information that the Consultant would normally freely disclose to other members of the scientific community at large, whether by publication, by presentation at seminars, or in informal scientific discussions. However, the Consultant shall not disclose to the Company information that (i) is proprietary to WHITEHEAD and (ii) is not generally available to the public, except through formal technology transfer procedures.
5. Subject to the terms of paragraph 6, below, the Consultant may assign to the Company any right, title and interest the Consultant may have in any invention, discovery, improvement, or other intellectual property which the Consultant

(whether alone or with others) develops (i) during the course of performing consulting services for the Company under the Agreement and (ii) outside the course of the Consultant's activities as a Member of WHITEHEAD.

6. The Company shall have no rights by reason of the Agreement in any publication, invention, discovery, improvement, or other intellectual property whatsoever, whether or not publishable, patentable, or copyrightable, which is developed as a result of a program of research financed, in whole or in part, by funds provided by or under the control of WHITEHEAD. The Company also acknowledges and agrees that it will enjoy no priority or advantage as a result of the consultancy created by the Agreement in gaining access, whether by license or otherwise, to any proprietary information or intellectual property that arises from any research undertaken by the Consultant in his or her capacity as a Member of WHITEHEAD.
7. The Company agrees, at its sole expense, to defend WHITEHEAD against, and to indemnify and hold WHITEHEAD harmless from, any claim, liability, judgment, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including without limitation reasonable attorneys' fees and other costs and expenses of defense) relating to a claim or suit by a third party against WHITEHEAD, either arising from the Agreement, the Consultant's performance of services for the Company under the Agreement, or any Company products or services which result from the Consultant's performance of services under the Agreement.
8. Nothing in the Agreement shall affect the Consultant's right to use, disseminate, or publish any information that (i) is or becomes available to the public through no breach of the Agreement by the Consultant; (ii) is obtained by the Consultant from a third party who had the legal right to disclose the information to the Consultant; (iii) is already in the possession of the Consultant on the date the Agreement becomes effective; or (iv) is required to be disclosed by law, government regulation, or court order, provided that the Consultant takes reasonable steps to provide the Company with sufficient prior notice to allow the Company to consent to the disclosure or seek a protective order. In addition, the Company's confidential information does not include information generated by the Consultant (whether alone or with others) unless the Consultant generated the information (i) during the course of performing consulting services for the Company under the Agreement and (ii) outside the course of the Consultant's activities as a Member of WHITEHEAD.
9. The Company acknowledges and agrees that nothing in the Agreement shall affect the Consultant's obligations to WHITEHEAD, the Consultant's research on behalf

of WHITEHEAD, or research collaborations in which the Consultant is a participant, and that the Agreement shall have no effect upon transfers (by way of license or otherwise) to third parties of materials or intellectual property developed in whole or in part by the Consultant as a Member of WHITEHEAD.

10. Paragraphs 7, 8, 9, 10, 12, 13, and 14 of these Uniform Provisions shall survive termination of the Agreement.
11. The Company may use the Consultant's name, and in doing so may cite the Consultant's relationship with WHITEHEAD, so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of the Company or of any Company program, product or service. However, the Company shall not use the Consultant's name or WHITEHEAD's name in any press release, or quote the Consultant in any company materials, or otherwise use the Consultant's name or WHITEHEAD's name in a manner not specifically permitted by the preceding sentence, unless in each case the Company obtains in advance WHITEHEAD's written consent, and, in the case of the use of the Consultant's name, the Consultant's consent as well.
12. The Consultant and the Company acknowledge that (i) the Consultant is entering into the Agreement and these Uniform Provisions in the Consultant's individual capacity and not as a Member of WHITEHEAD, (ii) WHITEHEAD is not a party to the Agreement or the Uniform Provisions and has no liability or obligation under them, and (iii) WHITEHEAD is an intended third-party beneficiary of the Agreement and certain provisions of the Agreement and the Uniform Provisions are for WHITEHEAD's benefit and are enforceable by WHITEHEAD in its own name.
13. The Uniform Provisions shall be in effect for the full term of the Agreement. The Company and the Consultant agree that any amendment of the Agreement (including, without limitation, any extension of the Agreement's term or any change in the consideration to be provided to the Consultant under the Agreement) or any other departure from the terms or conditions of the Agreement must be signed by the Consultant and an authorized representative of the Company, and also is subject to WHITEHEAD's prior written approval.
14. If any of these Uniform Provisions is adjudicated to be invalid, unenforceable, contrary to, or prohibited under applicable laws or regulations of any jurisdiction, the Agreement shall terminate as of the date such adjudication is effective.

COMPANY

VL42, Inc.

By: /s/ David A. Berry  
David A. Berry, M.D., Ph.D., President

CONSULTANT

By: /s/ Richard A. Young  
Richard A. Young, Ph.D.

**Annex 1**

**Other Relationships**

Syros Pharmaceuticals, Inc.  
Marauder Therapeutics, Inc.

October 29, 2021

Richard A. Young, Ph.D.

[XXX]

[XXX]

Re: **Amendment to Consulting Agreement**

Dear Richard:

This is in reference to the Consulting Agreement between VL42, d/b/a Omega Therapeutics, Inc., and Richard A. Young, Ph.D. dated November 7, 2016 (the "Agreement"). All capitalized terms used in this letter and not otherwise defined in this letter shall have the same meaning as in the Agreement.

Whereas the parties to the Agreement have agreed to extend the term of the Agreement through November 7, 2022, the parties hereby amend and restate Section 2 of the Agreement in its entirety, to read as follows:

2. Term. This Agreement shall commence on the Effective Date hereof and shall continue until November 7, 2022 unless sooner terminated in accordance with the provisions of Section 4 herein or unless further extended by mutual written consent of the parties (such period being referred to as the "Consultation Period").

Please sign below to confirm you agree with this Amendment, and kindly return a copy of the signed letter to us.

Sincerely,

/s/ Mahesh Karande

Mahesh Karande  
President and CEO  
Omega Therapeutics, Inc.

Agreed:

/s/ Richard A. Young

Name: Richard A. Young, Ph.D.

**LEASE AGREEMENT**

THIS LEASE AGREEMENT (this "**Lease**") is made this 4<sup>th</sup> day of November, 2021, between **ARE-MA REGION NO. 94, LLC**, a Delaware limited liability company ("**Landlord**"), and **OMEGA THERAPEUTICS, INC.**, a Delaware corporation ("**Tenant**").

**Premises:** That portion of the Building containing approximately 89,246 rentable square feet, consisting of (i) approximately 78,380 rentable square feet in Suite 501, chemical storage rooms CC5 and RC5, and penthouse storage room PH5 (collectively, the "**Phase 1 Premises**"), and (ii) approximately 10,866 rentable square feet in Suite 105 (the "**Phase 2 Premises**"), all as determined by Landlord, as shown on **Exhibit A**. The rentable square footage of the Premises has been determined in accordance with the Standard Method of Measuring Floor Area in Office Buildings as adopted by the Building Owners and Managers Association International (ANSI/BOMA Z65.1- 2017, Method B), as customarily modified for laboratory properties in the Cambridge, Massachusetts market.

**Building:** That certain building in the Project currently being redeveloped and known as One Charles Park, Cambridge, Massachusetts, and located on the real property owned by Landlord and described on **Exhibit B**.

**Project:** The real property on which the Building in which the Premises are located, together with all improvements thereon and appurtenances thereto as described on **Exhibit B**.

**Base Rent:** \$115.00 per rentable square foot of the Premises per year, subject to adjustment pursuant to Section 4 hereof.

**Rentable Area of Premises:** 89,246 sq. ft. **Rentable Area of Building:** 408,259 sq. ft. **Rentable Area of Project:** 408,259 sq. ft.

**Tenant's Share of Operating Expenses of Building:** 21.86% (19.20% with respect to the Phase 1 Premises and 2.66% with respect to the Phase 2 Premises)

**Security Deposit:** None

**Phase 1 Target Commencement Date:** December 15, 2022

**Phase 2 Target Commencement Date:** March 15, 2023

**Rent Adjustment Percentage:** 3%

**Base Term:** Beginning on the Commencement Date and ending 180 months from the first day of the first full month following the Commencement Date. For clarity, if the Commencement Date occurs on the first day of a month, the expiration of the Base Term shall be measured from that date. If the Commencement Date occurs on a day other than the first day of a month, the expiration of the Base Term shall be measured from the first day of the following month.

**Permitted Use:** Research and development laboratory, general office and other related uses consistent with the character of the Project and otherwise in compliance with the provisions of Section 7 hereof.

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**Address for Rent Payment:**

To be provided to Tenant prior to the Commencement Date

**Landlord's Notice Address:**

26 North Euclid Avenue  
Pasadena, CA 91101  
Attention: Corporate Secretary

**Tenant's Notice Address:**

Prior to the Commencement Date:  
c/o Flagship Pioneering  
55 Cambridge Parkway, Suite 800E  
Cambridge, MA 02142  
Attn: Barbara Chan

Following the Commencement Date:  
One Charles Park  
Cambridge MA 02142  
Attn: Barbara Chan

In all events with a copy to:

VentureLabs VI, Inc. c/o  
Flagship Pioneering  
55 Cambridge Parkway, Suite 800E  
Cambridge, MA 02142  
Attn: One Charles Park Coordinator

As a courtesy, copies of notices provided by Landlord to Tenant under this Lease shall be sent to [bchan@omegatherapeutics.com](mailto:bchan@omegatherapeutics.com) and [OCPLeaseCoordinator@flagshippioneering.com](mailto:OCPLeaseCoordinator@flagshippioneering.com).

The following Exhibits and Addenda are attached hereto and incorporated herein by this reference:

- EXHIBIT A** - PREMISES DESCRIPTION
- EXHIBIT B** - DESCRIPTION OF PROJECT
- EXHIBIT C** - WORK LETTER
- EXHIBIT D** - COMMENCEMENT DATE
- EXHIBIT E** - RULES AND REGULATIONS
- EXHIBIT F** - TENANT'S PERSONAL PROPERTY
- EXHIBIT G** - SHARED SPACE CONSENT

**1. Lease of Premises.** Upon and subject to all of the terms and conditions of this Lease, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The portions of the Project which are for the non-exclusive use of tenants of the Building are collectively referred to herein as the "**Common Areas**." Subject to the terms and conditions of this Lease, Tenant shall have the appurtenant right to use the Common Areas for their intended uses. The Common Areas shall include, without limitation, the common loading areas located in and serving the Building, any public or common lobbies, common chases and conduits, mechanical and utility rooms, hallways, stairways, elevators and common walkways, common toilets, corridors and elevator lobbies located on multi-tenant floors, pedestrian sidewalks, landscaped areas and trash enclosures, the exterior of the Project, the loading area, and any bicycle parking and storage areas. The Common Areas shall include, without limitation, any amenities now or hereafter located in, on or otherwise serving the Project, if any, as may exist from time to time (as determined by Landlord or affiliates of Landlord, in Landlord's (or Landlord's affiliate's) sole and absolute discretion) and made available, except for temporary interruptions and/or Force Majeure (as defined in Section 34), for use by Tenant and one or more other tenants of the Project and/or third parties (each, a "**Project Amenity**" and collectively, the "**Project Amenities**"). Landlord shall consider reasonable input from Tenant regarding the nature of future Project Amenities to be made available at the Building considering the workforce demographics of Tenant and other companies leasing space in the Building, but all decisions relating to such Project Amenities shall remain in the sole discretion of Landlord. Landlord reserves the right to modify Common Areas, provided that such modifications do not materially adversely affect Tenant's access to or use of the Premises for the Permitted Use. From and after the Commencement Date through the expiration of the Term, Tenant shall have access to the Building and the Premises 24 hours a day, 7 days a week, except in the case of emergencies, as the result of Legal Requirements, the performance by Landlord of any installation, maintenance or repairs, or any other temporary interruptions, and otherwise subject to the terms of this Lease.

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**2. Delivery; Acceptance of Premises; Commencement Date.**

(a) **Phase 1 Premises.** Landlord shall use commercially reasonable efforts to deliver the Phase 1 Premises to Tenant on or before the Phase 1 Target Commencement Date, with Landlord's Work related to the Phase 1 Premises Substantially Completed ("**Delivery**" or "**Deliver**"). If Landlord fails to timely Deliver the Phase 1 Premises, Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable except as provided herein. Notwithstanding anything to the contrary contained herein, if Landlord fails to Deliver the Phase 1 Premises to Tenant within 60 days after the Phase 1 Target Commencement Date (as such date may be extended by Force Majeure delays and Tenant Delays, the "**Phase 1 Abatement Date**"), Base Rent payable with respect to the Phase 1 Premises shall be abated 1 day for each day after the Phase 1 Abatement Date that Landlord fails to Deliver the Phase 1 Premises to Tenant. If Landlord does not Deliver the Phase 1 Premises within 180 days of the Phase 1 Target Commencement Date for any reason other than Force Majeure and Tenant Delays, this Lease may be terminated by Tenant by written notice to Landlord, and if so terminated by Tenant, neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions which expressly survive termination of this Lease. As used herein, the terms "**Landlord's Work**," "**Tenant Delays**" and "**Substantially Completed**" shall have the meanings set forth for such terms in the Work Letter. If Tenant does not elect to void this Lease within 5 business days of the lapse of such 180 day period set forth in this paragraph, such right to void this Lease shall be waived and this Lease shall remain in full force and effect. Until the Phase 2 Premises Commencement Date (as defined in Section 2(b)) occurs, all references to "Premises" in the Lease shall mean the Phase 1 Premises.

The "**Commencement Date**" shall be the earlier of: (i) the date Landlord Delivers the Phase 1 Premises to Tenant; and (ii) the date Landlord could have Delivered the Phase 1 Premises but for Tenant Delays.

Except as set forth in the Work Letter or as otherwise expressly set forth in this Lease: (i) Tenant shall accept the Phase 1 Premises in their condition as of the Commencement Date; (ii) Landlord shall have no obligation for any defects in the Phase 1 Premises; and (iii) Tenant's taking possession of the Phase 1 Premises shall be conclusive evidence that Tenant accepts the Phase 1 Premises and that the Phase 1 Premises were in good condition at the time possession was taken. Any occupancy of the Phase 1 Premises by Tenant before the Commencement Date shall be subject to all of the terms and conditions of this Lease, excluding, so long as Tenant is not conducting business in any portion of the Phase 1 Premises, the obligation to pay Base Rent and Operating Expenses with respect to the Phase 1 Premises.

For the period of 90 consecutive days after the Commencement Date, Landlord shall, at its sole cost and expense (which shall not constitute an Operating Expense), be responsible for any repairs that are required to be made to the Building or Building Systems (as defined in Section 13) serving the Phase 1 Premises, unless Tenant or any Tenant Party was responsible for the cause of such repair, in which case Tenant shall pay the cost. Tenant shall also have the benefit of any warranties issued to Landlord in connection with Landlord's Work related to the Phase 1 Premises.

(b) **Phase 2 Premises.** Landlord shall use commercially reasonable efforts to Deliver the Phase 2 Premises to Tenant on or before the Phase 2 Target Commencement Date, with Landlord's Work related to the Phase 2 Premises Substantially Completed. If Landlord fails to timely Deliver the Phase 2 Premises, Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable. Notwithstanding anything to the contrary contained herein, if Landlord fails to Deliver the Phase 2 Premises to Tenant within 60 days after the Phase 2 Target Commencement Date (as such date may be extended by Force Majeure delays and Tenant Delays, the "**Phase 2 Abatement Date**"), Base Rent payable with respect to the Phase 2 Premises shall be abated 1 day for each day after the Phase 2 Abatement Date that Landlord fails to Deliver the Phase 2 Premises to Tenant.

"**Phase 2 Commencement Date**" shall be the earlier of: (i) the date Landlord Delivers the Phase 2 Premises to Tenant; and (ii) the date Landlord could have Delivered the Phase 2 Premises but for Tenant Delays.

Except as set forth in the Work Letter or as otherwise expressly set forth in this Lease: (i) Tenant

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shall accept the Phase 2 Premises in their condition as of the Phase 2 Commencement Date; (ii) Landlord shall have no obligation for any defects in the Phase 2 Premises; and (iii) Tenant's taking possession of the Phase 2 Premises shall be conclusive evidence that Tenant accepts the Phase 2 Premises and that the Phase 2 Premises were in good condition at the time possession was taken. Any occupancy of the Phase 2 Premises by Tenant before the Phase 2 Commencement Date shall be subject to all of the terms and conditions of this Lease, excluding, so long as Tenant is not conducting business in any portion of the Phase 2 Premises, the obligation to pay Base Rent and Operating Expenses with respect to the Phase 2 Premises.

For the period of 90 consecutive days after the Phase 2 Commencement Date, Landlord shall, at its sole cost and expense (which shall not constitute an Operating Expense), be responsible for any repairs that are required to be made to the Building or Building Systems serving the Phase 2 Premises, unless Tenant or any Tenant Party was responsible for the cause of such repair, in which case Tenant shall pay the cost. Tenant shall also have the benefit of any warranties issued to Landlord in connection with Landlord's Work related to the Phase 2 Premises.

(c) **Generally.**

Upon request of Landlord, Tenant shall execute and deliver a written acknowledgment of the Commencement Date, the Phase 2 Commencement Date, and the expiration date of the Term when such are established in the form of the "Acknowledgement of Commencement Date" attached to this Lease as **Exhibit D**; provided, however, Tenant's failure to execute and deliver such acknowledgment shall not affect Landlord's rights hereunder. The "**Term**" of this Lease shall be the Base Term, as defined above on the first page of this Lease and any Extension Terms which Tenant may elect pursuant to Section 39 hereof.

Tenant agrees and acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of all or any portion of the Premises or the Project, and/or the suitability of the Premises or the Project for the conduct of Tenant's business, and Tenant waives any implied warranty that the Premises or the Project are suitable for the Permitted Use. Landlord represents and warrants that the person signing this Lease on behalf of Landlord is duly authorized to execute and deliver this Lease on behalf of Landlord as a legally binding contract of Landlord. Tenant represents and warrants that the person signing this Lease on behalf of Tenant is duly authorized to execute and deliver this Lease on behalf of Tenant as a legally binding contract of Tenant. This Lease constitutes the complete agreement of Landlord and Tenant with respect to the subject matter hereof and supersedes any and all prior representations, inducements, promises, agreements, understandings and negotiations which are not contained herein. Landlord in executing this Lease does so in reliance upon Tenant's representations, warranties, acknowledgments and agreements contained herein.

Notwithstanding anything to the contrary contained in this Lease, Tenant and Landlord acknowledge and agree that as of the date of this Lease, Landlord does not own the Project and that the effectiveness of this Lease and the delivery of the Premises to Tenant is conditioned upon Landlord acquiring fee title to the Project or entering into a master lease to become the master lessee of the Project pursuant to the existing purchase and sale agreement (as the same may be amended) between Landlord and the current owner of the Project ("**Condition Precedent**"). Neither Landlord nor Tenant shall have any liability whatsoever to each other relating to or arising from Landlord's inability or failure for any reason to cause the Condition Precedent to be satisfied. If the Condition Precedent is not satisfied by January 26, 2022, then this Lease may be terminated by Landlord or Tenant by delivery of written notice to the other delivered on or before February 2, 2022. If this Lease terminates pursuant to the

immediately preceding sentence, neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease: (a) the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), and any prepaid Base Rent shall be returned to Tenant, and (b) neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions which expressly survive termination of this Lease.

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### 3. Rent.

(a) **Base Rent.** The first full month's Base Rent for each of the Phase 1 Premises and the Phase 2 Premises shall be due and payable concurrently with Tenant's delivery of an executed copy of this Lease to Landlord. Tenant shall pay to Landlord in advance, without demand, abatement, deduction or set-off, monthly installments of Base Rent on or before the first day of each calendar month during the Term hereof after the Commencement Date with respect to the Phase 1 Premises and after the Phase 2 Commencement Date with respect to the Phase 2 Premises, in lawful money of the United States of America, at the office of Landlord for payment of Rent set forth above, or to such other person or at such other place as Landlord may from time to time designate in writing, or via federally insured wire transfer (including ACH) pursuant to the wire instructions provided by Landlord. Payments of Base Rent for any fractional calendar month shall be prorated. The obligation of Tenant to pay Base Rent and other sums to Landlord and the obligations of Landlord under this Lease are independent obligations. Tenant shall have no right at any time to abate, reduce, or set-off any Rent (as defined in Section 5) due hereunder except for any abatement as may be expressly provided in this Lease.

(b) **Additional Rent.** In addition to Base Rent, Tenant agrees to pay to Landlord as additional rent ("**Additional Rent**"): (i) commencing on (x) the Commencement Date with respect to the Phase 1 Premises, and (y) the Phase 2 Commencement Date with respect to the Phase 2 Premises, Tenant's Share of "Operating Expenses" (as defined in Section 5), and (ii) any and all other amounts Tenant assumes or agrees to pay under the provisions of this Lease, including, without limitation, any and all other sums that may become due by reason of any default of Tenant or failure to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after any applicable notice and cure period.

### 4. Base Rent Adjustments.

(a) **Annual Adjustments.** Base Rent shall be increased on each annual anniversary of the Commencement Date (provided, however, that if the Commencement Date occurs on a day other than the first day of a calendar month, then Base Rent shall be increased on each annual anniversary of the first day of the first full calendar month immediately following the Commencement Date) (each an "**Adjustment Date**") by multiplying the Base Rent payable immediately before such Adjustment Date by the Rent Adjustment Percentage and adding the resulting amount to the Base Rent payable immediately before such Adjustment Date. Base Rent, as so adjusted, shall thereafter be due as provided herein. Base Rent adjustments for any fractional calendar month shall be prorated.

(b) **Additional TI Allowance.** In addition to the Tenant Improvement Allowance (as defined in the Work Letter), Landlord shall, subject to the terms of the Work Letter, make available to Tenant the Additional Tenant Improvement Allowance (as defined in the Work Letter). Commencing on the Commencement Date and continuing thereafter on the first day of each month during the Base Term, Tenant shall pay the amount necessary to fully amortize the portion of the Additional Tenant Improvement Allowance actually funded by Landlord, if any, in equal monthly payments with annual interest at a rate of 8% per annum over the Base Term, which interest shall begin to accrue on the date that Landlord first disburses such Additional Tenant Improvement Allowance or any portion(s) thereof ("**TI Rent**"). Any TI Rent remaining unpaid as of the expiration or earlier termination of this Lease shall be paid to Landlord in a lump sum at the expiration or earlier termination of this Lease. For the avoidance of doubt, TI Rent shall not be subject to adjustment pursuant to Section 4(a) above. Tenant may, at Tenant's option,

prepay the then-outstanding TI Rent (including applicable interest remaining unpaid) in full at any time without penalty.

**5. Operating Expense Payments.** Landlord shall deliver to Tenant a written estimate of Operating Expenses for each calendar year during the Term on or before the date that is 30 days prior to the first day of each calendar year (the "**Annual Estimate**"), which may be revised by Landlord from time to time during such calendar year. Commencing on the Commencement Date with respect to the Phase 1 Premises and on the Phase 2 Commencement Date with respect to the Phase 2 Premises, and continuing

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thereafter on the first day of each month during the Term, Tenant shall pay Landlord an amount equal to 1/12th of Tenant's Share of the Annual Estimate. Payments for any fractional calendar month shall be prorated.

The term "**Operating Expenses**" means all costs and expenses of any kind or description whatsoever incurred or accrued each calendar year by Landlord with respect to the Building including, without duplication, (i) Taxes (as defined in Section 9), (ii) the cost of upgrades to the Building or Project or enhanced services provided at the Building and/or Project which are intended to encourage social distancing, promote and protect health and physical well-being and/or intended to limit the spread of communicable diseases and/or viruses of any kind or nature (collectively, "**Infectious Conditions**"), (iii) the cost (including, without limitation, any commercially reasonable subsidies which Landlord may provide in connection with the Project Amenities) of the Project Amenities, (iv) costs related to the parking structures and/or other parking areas serving the Project and transportation costs (including costs associated with Landlord's operation of or participation in a shuttle service serving the Project, if any), (v) capital repairs, improvements and replacements amortized over the lesser of 10 years and the useful life of such capital repairs, improvements and replacements, and (vi) the costs of Landlord's third party property manager (not to exceed 3% of Base Rent) or, if there is no third party property manager, administration rent in the amount of 3% of Base Rent, excluding only:

(a) the original construction costs of the Project, including the Base Building Improvements (as defined in the Work Letter) and renovation prior to the Commencement Date and costs of correcting defects in such original construction or renovation;

(b) expenditures for design, permitting, construction or related costs for the expansion of the Project;

(c) interest, principal payments of Mortgage (as defined in Section 27) debts of Landlord, financing costs and amortization of funds borrowed by Landlord, whether secured or unsecured and all payments of base rent (but not taxes or operating expenses) under any ground lease or other underlying lease of all or any portion of the Project;

(d) depreciation of the Project (except for capital improvements, the cost of which are includable in Operating Expenses);

(e) advertising, legal and space planning expenses and leasing commissions and other costs and expenses incurred in procuring and leasing space to tenants for the Project, including any leasing office maintained in the Project, free rent and construction allowances for tenants;

(f) legal and other expenses incurred in the negotiation or enforcement of leases;

(g) completing, fixturing, improving, renovating, painting, redecorating or other work, which Landlord pays for or performs for other tenants within their premises, and costs of correcting defects in such work;

(h) costs to be reimbursed by other tenants of the Project or Taxes to be paid directly by Tenant or other tenants of the Project, whether or not actually paid;

(i) salaries, wages, benefits and other compensation paid to (i) personnel of Landlord or its agents or contractors above the position of the person, regardless of title, who has day-to-day management responsibility for the Project or (ii) officers and employees of Landlord or its affiliates who are not assigned in whole or in part to the operation, management, maintenance or repair of the Project; provided, however, that with respect to any such person who does not devote substantially all of his or her employed time to the Project, the salaries, wages, benefits and other compensation of such person shall be prorated to reflect time spent on matters related to operating, managing, maintaining or repairing the Project in comparison to the time spent on matters unrelated to operating, managing, maintaining or repairing the Project;

(j) general organizational, administrative and overhead costs relating to maintaining Landlord's

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existence, either as a corporation, partnership, or other entity, including general corporate, legal and accounting expenses;

(k) costs (including attorneys' fees and costs of settlement, judgments and payments in lieu thereof) incurred in connection with disputes with tenants, other occupants, or prospective tenants, and costs and expenses, including legal fees, incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building or Property;

(l) costs incurred by Landlord due to the violation by Landlord, its employees, agents or contractors or any tenant of the terms and conditions of any lease of space in the Project or any Legal Requirement (as defined in Section Z);

(m) penalties, fines or interest incurred as a result of Landlord's inability or failure to make payment of Taxes and/or to file any tax or informational returns when due, or from Landlord's failure to make any payment of Taxes required to be made by Landlord hereunder before delinquency;

(n) overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in or to the Project to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third parties on a competitive basis;

(o) costs of Landlord's charitable or political contributions, or of fine art maintained at the Project;

(p) costs in connection with services (including electricity), items or other benefits of a type which are not standard for the Project and which are not available to Tenant without specific charges therefor, but which are provided to another tenant or occupant of the Project, whether or not such other tenant or occupant is specifically charged therefor by Landlord;

(q) costs incurred in the sale or refinancing of the Project (or any portion thereof);

(r) net income taxes of Landlord or the owner of any interest in the Project, franchise, capital stock, gift, estate or inheritance taxes or any federal, state or local documentary taxes imposed against the Project or any portion thereof or interest therein;

(s) costs or expenses otherwise includable in Operating Expenses to the extent actually reimbursed by insurance policies required to be maintained by Landlord in accordance with Section 17;

(t) Operating Expense reserves (other than reserves for Taxes for the then-current year);

(u) rentals of equipment ordinarily considered to be of a capital nature (such as elevators and HVAC systems) except if such equipment is reasonably and customarily leased either temporarily or permanently in the operation of comparable office and laboratory buildings in the Cambridge area;

(v) any costs or expenses that are duplicative of maintenance and repair costs and expenses actually paid by Tenant in satisfaction of Tenant's maintenance and repair obligations pursuant to this Lease;

(w) costs or expenses occasioned by condemnation that are actually recovered by Landlord in any condemnation awards;

(x) costs reimbursable to Landlord under any warranty carried by Landlord for the Building or the Project or any portion thereof;

(y) costs arising from the gross negligence or willful misconduct of Landlord or its agents, and employees;

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(z) any costs incurred to remove, study, test or remediate Hazardous Materials in or about the Premises, the Building or the Project for which Tenant is not responsible under Section 30 hereof;

(aa) the costs of signs at the Project identifying Landlord or any other tenants of the Project;

(bb) any expenses applicable to applying and reporting for the Building or the Project solely for the purpose of seeking or maintaining a Leadership in Energy and Environmental Design (LEED), WELL Building Standard, or other similar "green" certification rating above a gold standard or its equivalent;

(cc) costs associated with the maintenance or operation of the Charles Park Garage (as defined in Section 10) or other parking facilities serving the Building or the Project or any portion thereof; and

(dd) any expenses otherwise includable within Operating Expenses to the extent actually reimbursed by persons other than tenants of the Project under leases for space in the Project.

In addition, notwithstanding anything to the contrary contained in this Lease, Operating Expenses incurred or accrued by Landlord with respect to any capital improvements which are reasonably expected by Landlord to reduce overall Operating Expenses (for example, without limitation, by reducing energy usage at the Project) (the "**Energy Savings Costs**") shall be amortized over a period of years equal to the least of (A) 10 years, (B) the useful life of such capital items, or (C) the quotient of (i) the Energy Savings Costs, divided by (ii) the annual amount of Operating Expenses reasonably expected by Landlord to be saved as a result of such capital improvements.

Within 90 days after the end of each calendar year (or such longer period as may be reasonably required), Landlord shall furnish to Tenant a statement (an "**Annual Statement**") showing in reasonable detail: (a) the total and Tenant's Share of actual Operating Expenses for the previous calendar year, and (b) the total of Tenant's payments in respect of Operating Expenses for such year. If Tenant's Share of actual Operating Expenses for such year exceeds Tenant's payments of Operating Expenses for such year, the excess shall be due and payable by Tenant as Rent within 30 days after delivery of such Annual Statement to Tenant. If Tenant's payments of Operating Expenses for such year exceed Tenant's Share of actual Operating Expenses for such year Landlord shall pay the excess to Tenant within 30 days after delivery of such Annual Statement, except that after the expiration, or earlier termination of the Term or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord.

Following the date that is 18 months after Landlord's delivery of an Annual Statement to Tenant, Tenant shall not be responsible for the payment of items of Operating Expenses not reflected in such Annual Statement, except for Taxes for which Tenant is responsible under this Lease and/or any costs for which Landlord is billed after the expiration of such 18 month period.

The Annual Statement shall be final and binding upon Tenant unless Tenant, within 120 days after Tenant's receipt thereof, shall contest any item therein by giving written notice to Landlord, specifying each item contested and the reason therefor. If, during such 120 day period, Tenant reasonably and in good faith questions or contests the accuracy of Landlord's statement of Tenant's Share of Operating Expenses, Landlord will provide Tenant with access to Landlord's books and records relating to the operation of the Project and such information as Landlord reasonably determines to be responsive to Tenant's questions (the "**Expense Information**"). If after Tenant's review of such Expense Information, Landlord and Tenant cannot agree upon the amount of Tenant's Share of Operating Expenses, then Tenant shall have the right to have a regionally or nationally recognized independent public accounting firm or an auditing firm selected by Tenant and approved by Landlord (which approval shall not be unreasonably withheld or delayed), working pursuant to a fee arrangement other than a contingent fee (at Tenant's sole cost and expense), audit and/or review the Expense Information for the year in question (the "**Independent Review**"). The results of any such Independent Review shall be binding on Landlord and Tenant. If the Independent Review shows that the payments actually made by Tenant with respect to Operating Expenses for the calendar year in question exceeded Tenant's Share of Operating Expenses for such calendar year, Landlord shall at Landlord's option either (i) credit the excess amount to the next succeeding installments

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of estimated Operating Expenses or (ii) pay the excess to Tenant within 30 days after delivery of such statement, except that after the expiration or earlier termination of this Lease or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord. If the Independent Review shows that Tenant's payments with respect to Operating Expenses for such calendar year were less than Tenant's Share of Operating Expenses for the calendar year, Tenant shall pay the deficiency to Landlord within 30 days after delivery of such statement. If the Independent Review shows that Tenant has overpaid with respect to Operating Expenses by more than 5% then Landlord shall reimburse Tenant for all costs incurred by Tenant for the Independent Review. Operating Expenses for the calendar years in which Tenant's obligation to share therein begins and ends shall be prorated. Notwithstanding anything set forth herein to the contrary, if the Building is not at least 95% occupied on average during any year of the Term, Tenant's Share of Operating Expenses for such year that vary with the level of occupancy of the Building shall be computed as though the Building had been 95% occupied on average during such year.

"**Tenant's Share**" shall be the percentage set forth in the Basic Lease Provisions as "Tenant's Share of Operating Expenses of Building," as may be reasonably adjusted by Landlord for changes in the physical size of the Premises, Building, and/or Project occurring thereafter. Landlord may equitably increase Tenant's Share for any Operating Expenses that relate to any item of expense or cost (1) equitably and reasonably allocated only to the Premises, the Building or Property, (2) equitably and reasonably allocated to only a portion of the Building, Property or Project that includes the Premises, or

(3) a greater proportion of which is equitably and reasonably allocated to the Premises, or a portion of the Building, Property or Project that includes the Premises, as reasonably determined by Landlord. Base Rent, Tenant's Share of Operating Expenses and all other amounts payable by Tenant to Landlord hereunder are collectively referred to herein as "**Rent**."

Tenant shall have the right, within 30 days after the TI Construction Drawings (as defined in the Work Letter) with respect to the entire Premises (including the Phase 2 Premises) have been finalized, to have the TI Architect verify the rentable square footage of the Premises ("**RSF Verification**"). Such RSF Verification shall be performed in accordance with the Measurement Standard, using the same methodologies and assumptions as applied by Stevenson Systems in connection with its determination of the rentable square footage of the Premises reflected on page 1 of this Lease. Upon the completion of the RSF Verification, Tenant shall deliver a copy of the results of the RSF Verification to Landlord. If the RSF Verification reflects a deviation from the rentable square footage of the Premises reflected in the definitions of "**Premises**" and "**Rentable Area of Premises**," on page 1 of this Lease then, promptly following Tenant's delivery of the results of the RSF Verification to Landlord, the definitions of "**Premises**" and "**Rentable Area of Premises**" (and, if applicable, as reasonably determined by Landlord, "**Rentable Area of Building**" and/or "**Rentable Area of Project**") on page 1 of this Lease, shall be amended so as to (i) reflect the actual rentable square footage thereof in the definitions of "**Premises**" and "**Rentable Area of Premises**" (and, if applicable, as reasonably determined by Landlord, "**Rentable Area of Building**" and/or "**Rentable Area of Project**"), and (ii) appropriately adjust the amount set forth in the definition of "**Tenant's Share of Operating Expenses of Building**," which were calculated based on the rentable square footages of the Premises, Building and Project originally set forth on page 1 of this Lease.

**6. Intentionally Omitted.**

**7. Use.**

(a) **Generally.** The Premises shall be used solely for the Permitted Use set forth in the basic lease provisions on page 1 of this Lease, and in compliance with all laws, orders, judgments, ordinances, regulations, codes, directives, permits, licenses, covenants and restrictions now or hereafter applicable to the Premises, and to the use and occupancy thereof, including, without limitation, the Americans With Disabilities Act, 42 U.S.C. § 12101, et seq. (together with the regulations promulgated pursuant thereto, "**ADA**") (collectively, "**Legal Requirements**" and each, a "**Legal Requirement**"). Tenant shall, upon 5 days' written notice from Landlord, discontinue any use of the Premises which is declared by any Governmental Authority (as defined in Section 9) having jurisdiction to be a violation of a Legal Requirement. Tenant will not use or permit the Premises to be used for any purpose or in any manner that would void Tenant's or

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Landlord's insurance, increase the insurance risk, or cause the disallowance of any sprinkler or other credits. The Permitted Use as defined in this Lease will not result in the voidance of or an increased insurance risk or cause the disallowance of any sprinkler or other credits with respect to the insurance currently being maintained by Landlord. Tenant shall not permit any part of the Premises to be used as a "place of public accommodation", as defined in the ADA or any similar legal requirement. Tenant shall reimburse Landlord promptly upon demand for any additional premium charged for any such insurance policy by reason of Tenant's failure to comply with the provisions of this Section or otherwise caused by Tenant's particular use and/or occupancy of the Premises. Tenant will use the Premises in a careful, safe and proper manner and will not commit or permit waste, overload the floor or structure of the Premises, subject the Premises to use that would damage the Premises or obstruct or interfere with the rights of Landlord or other tenants or occupants of the Project, including conducting or giving notice of any auction, liquidation, or going out of business sale on the Premises, or using or allowing the Premises to be used for any unlawful purpose. Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises from extending into Common Areas, or other space in the Project. Tenant shall not place any machinery or equipment which would overload the floor in or upon the Premises or transport or move such items through the Common Areas of the Project or in the Building elevators without the prior written consent of Landlord. Except as may be provided under the Work Letter, Tenant shall not, without the prior written consent of Landlord, , which consent shall not be unreasonably withheld, conditioned or delayed, use the Premises in any manner which will require ventilation, air exchange, heating, gas, steam, electricity or water beyond the existing capacity of the Building as proportionately allocated to the Premises based upon Tenant's Share as usually furnished for the Permitted Use.

Landlord shall be responsible, (i) subject to the terms of the Work Letter, for the compliance of the Phase 1 Premises with Legal Requirements (including the ADA) as of the Commencement Date, (ii) subject to the terms of the Work Letter, for the compliance of the Phase 2 Premises with Legal Requirements (including the ADA) as of the Phase 2 Commencement Date, and (iii) at Landlord's cost, for the compliance of the Common Areas of the Project with Legal Requirements (including the ADA) as of the Commencement Date. Following the Commencement Date, Landlord shall, as an Operating Expense (to the extent such Legal Requirement is generally applicable to similar buildings in the area in which the Project is located) or at Tenant's expense (to the extent such Legal Requirement is triggered by reason of Tenant's, as compared to other tenants of the Project, specific use of the Premises or Tenant's Alterations) make any alterations or modifications to the Common Areas or the exterior of the Building that are required by Legal Requirements. Except as otherwise expressly provided in the 2 immediately preceding sentences, Tenant, at its sole expense, shall make any alterations or modifications to the interior of the Premises that are required by Legal Requirements (including, without limitation, compliance of the Premises with the ADA) related to Tenant's particular use or occupancy of the Premises. Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgments, and all reasonable expenses incurred in investigating or resisting the same (including, without limitation, reasonable attorneys' fees, charges and disbursements and costs of suit) (collectively, "**Claims**") arising out of or in connection with Legal Requirements related to Tenant's particular use or occupancy of the Premises or Tenant's Alterations, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any failure of the Premises to comply with any Legal Requirements related to Tenant's particular use or occupancy of the Premises or Tenant's Alterations.

Tenant acknowledges that Landlord may, but shall not be obligated to, seek to obtain Leadership in Energy and Environmental Design (LEED), WELL Building Standard, or other similar "green" certification with respect to the Project and/or the Premises, and Tenant agrees to reasonably cooperate with Landlord, at no material cost to Tenant, and to provide such information and/or documentation as Landlord may reasonably request, in connection therewith.

(b) **Energy Use Reporting.** Tenant agrees to provide, within 10 business days of written request by Landlord, such information and documentation within Tenant's reasonable control as may be needed for compliance with the City of Cambridge Building Energy Use Disclosure Ordinance, Section 8.67.010 et seq. of the Municipal Code of the City of Cambridge (as the same may be amended, the "**Cambridge Building Energy Use Disclosure Ordinance**"), and other such energy or sustainability

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requirements as may be adopted from time to time by the City of Cambridge or any other governmental authority with jurisdiction over the Building, which information shall include without limitation usage at or by the Premises of electricity, natural gas, steam, hot or chilled water or other energy. Landlord shall report to the applicable governmental authority such energy usage for the Building and other Building information as required by the Cambridge Building Energy Use Disclosure Ordinance.

**8. Holding Over.** If, with Landlord's express written consent, Tenant retains possession of the Premises after the termination of the Term, (i) unless otherwise agreed in such written consent, such possession shall be subject to immediate termination by Landlord at any time, (ii) all of the other terms and provisions of this Lease (including, without limitation, the adjustment of Base Rent pursuant to Section 4 hereof) shall remain in full force and effect (excluding any expansion or renewal option or other similar right or option) during such holdover period, (iii) Tenant shall continue to pay Base Rent in the amount payable upon the date of the expiration or earlier termination of this Lease or such other amount as Landlord may indicate, in Landlord's sole and absolute discretion, in such written consent, and (iv) all other payments shall continue under the terms of this Lease. If Tenant remains in possession of the Premises after the expiration or earlier termination of the Term without the express written consent of Landlord, (A) Tenant shall become a tenant at sufferance upon the terms of this Lease except that the monthly rental shall be equal to 150% of Rent in effect during the last 30 days of the Term, and (B) if such occupancy shall continue for more than 60 days, Tenant shall be responsible for all damages suffered by Landlord resulting from or occasioned by Tenant's holding over, including consequential damages; provided, however, that if Tenant delivers a written inquiry to Landlord within 30 days prior to the expiration or earlier termination of the Term, Landlord will notify Tenant whether the potential exists for consequential damages. No holding over by Tenant, whether with or without consent of Landlord, shall operate to extend this Lease except as otherwise expressly provided, and this Section 8 shall not be construed as consent for Tenant to retain possession of the Premises. Acceptance by Landlord of Rent after the expiration of the Term or earlier termination of this Lease shall not result in a renewal or reinstatement of this Lease.

**9. Taxes.** Landlord shall pay, as part of Operating Expenses, all taxes, levies, fees, assessments and governmental charges of any kind, existing as of the Commencement Date or thereafter enacted (collectively referred to as "**Taxes**"), imposed by any federal, state, regional, municipal, local or other governmental authority or agency, including, without limitation, quasi-public agencies (collectively, "**Governmental Authority**") during the Term, including, without limitation, all Taxes: (i) imposed on or measured by or based, in whole or in part, on rent payable to (or gross receipts received by) Landlord under this Lease and/or from the rental by Landlord of the Building, Property or Project or any portion thereof, or (ii) based on the square footage, assessed value or other measure or evaluation of any kind of the Premises, Building, Property or Project or portion thereof, or (iii) assessed or imposed by or on the operation or maintenance of any portion of the Premises, Building, Property or Project, including parking, or (iv) assessed or imposed by, or at the direction of, or resulting from Legal Requirements, or interpretations thereof, promulgated by, any Governmental Authority, or (v) imposed as a license or other fee, charge, tax or assessment on Landlord's business or occupation of leasing space in the Building, Property or Project or portion thereof. Landlord may contest by appropriate legal proceedings the amount, validity, or application of any Taxes or liens securing Taxes. If Landlord secures an abatement or refund for the Project for a period during the Term, Tenant shall receive Tenant's Share of such abatement or refund (i.e., the net amount after paying all reasonable costs and expenses of securing the abatement or refund, including reasonable attorneys' fees) as credit to be applied by Landlord against Operating Expenses next coming due (or, if no further Operating Expenses are due from Tenant under this Lease and Tenant is not in Default under this Lease, a cash payment to Tenant). Taxes shall not include any net income taxes or franchise, estate, inheritance, succession, gift or excess profit taxes imposed on Landlord except to the extent such taxes are in substitution for any Taxes payable hereunder, or any penalties for late payment of Taxes. If any such Tax is levied or assessed directly against Tenant, then Tenant shall be responsible for and shall pay the same at such times and in such manner as the taxing authority shall require. Operating Expenses hereunder shall also include the cost of tax monitoring services provided to Landlord with respect to the Building, Property or Project. Tenant shall pay, prior to delinquency, any and all Taxes levied or assessed against any personal property or trade fixtures placed by Tenant in the Premises, whether levied or assessed against Landlord or Tenant. If any Taxes on Tenant's personal property or trade fixtures are levied against Landlord or Landlord's property, or if the assessed valuation of the Building, Property or

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Project is increased by a value attributed by the applicable taxing authority to improvements in or alterations to the Premises, whether owned by Landlord or Tenant and whether or not affixed to the real property so as to become a part thereof, higher than the base valuation on which Landlord from time-to-time allocates Taxes to all tenants in the Building, Property or Project, or portion thereof of which the Premises are a part, Landlord shall have the right, but not the obligation, to pay such Taxes. Landlord's reasonable determination of any excess assessed valuation shall be binding and conclusive, absent manifest error. The amount of any such payment by Landlord shall constitute Additional Rent due from Tenant to Landlord within 30 days of Landlord's written demand.

#### 10. Parking and PTDM.

(a) **Parking and Monthly Parking Charge.** Subject to all applicable Legal Requirements, Force Majeure, or a Taking (as defined in Section 19 below), commencing on the Commencement Date with respect to the Phase 1 Premises and on the Phase 2 Commencement Date with respect to the Phase 2 Premises, Tenant shall be allocated (and shall be required to pay Monthly Parking Charges (as defined below) for) 1.0 parking spaces per 1,000 rentable square feet of the Premises ("**Tenant's Parking Allocation**") in the parking facility serving the Building (the "**Charles Park Garage**"), which parking spaces shall be located in those areas designated for non-reserved parking, subject in each case to Landlord's rules and regulations. Parking spaces within the Charles Park Garage in excess (i) of the number of parking spaces required to meet the parking allocation of the tenants of the Building (1.0 parking space per 1,000 per rentable square feet of space leased by each such tenant), plus (ii) the number of parking spaces allocated, as determined by Landlord in its sole and absolute discretion, for "guest" parking, shall be designated as a "**Surplus Parking Pool**" and parking spaces from the Surplus Parking Pool shall be proportionately allocated to tenants of the Building, subject to each tenant's payment of Monthly Parking Charges for all such additional parking spaces from the Surplus Parking Pool. Notwithstanding the foregoing, Landlord shall have the right at any time upon written notice to the tenants of the Building, including Tenant, to reduce the number of parking spaces included as part of the Surplus Parking Pool or to eliminate the Surplus Parking Pool, in connection with any development or redevelopment by Landlord or any affiliate of Landlord at the Project, including any expansion thereof. Landlord shall not be responsible for enforcing Tenant's parking rights against any third parties, including other tenants of the Project. The "**Monthly Parking Charge**" shall mean the market rate monthly charge therefor designated by Landlord, adjusted reasonably and no more frequently than once in any 12-month period, based upon the rates charged by comparable parking facilities in the vicinity of the Project, which Monthly Parking Charge is anticipated as of the Commencement Date to be equal to \$450.00 per space per month, plus applicable taxes.

(b) **Parking and Transportation Demand Management.** There is currently no PTDM (as defined below) in place for the Project. If a PTDM is implemented at any time, Tenant shall, at Tenant's sole expense, for so long as a parking and traffic demand management plan approved by the City of Cambridge (as amended from time to time, the "**PTDM**"), is applicable to the Project, comply with the PTDM as applicable to the Project, including without limitation, as applicable (i) offer to subsidize mass transit monthly passes for all of its employees who work in the Premises in accordance with the terms set forth in the PTDM; (ii) implement a Commuter Choice Program and the MBTA's Corporate Pass Plan; (iii) discourage single-occupant vehicle ("**SOV**") use by its employees; (iv) promote alternative modes of transportation and use of alternative work hours; (v) at Landlord's request, meet with Landlord and/or its representatives no more frequently than quarterly to discuss transportation programs and initiatives; (vi) participate in annual surveys, monitoring transportation programs and initiatives at the Campus, and, without limitation, achieve a sixty (60%) percent response rate for patron surveys; (vii) cooperate with Landlord in connection with transportation programs and initiatives promulgated pursuant to the PTDM; (viii) provide alternative work programs (such as telecommuting, flex-time and compressed work weeks) to its employees in order to reduce traffic impacts in Cambridge during peak commuter hours; (ix) offer an emergency ride home ("**ERH**") through the Charles River Transportation Management Association ("**CRTMA**"), or have its own ERH program, for all employees who commute by non-SOV mode at least 3 days a week and who are eligible to park in the parking spaces in the parking facility described above; (x) cooperate with the Cambridge Office of Workforce Development to expand employment opportunities for Cambridge residents; (xi) become a member of the CRTMA and cause the EZ Ride shuttle service to service the Building; (xii) in the event that the single occupancy vehicle and traffic generation modal split

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limits of the PTDM are exceeded, charge each user of a parking space the market rate for parking in Kendall Square/East Cambridge therefor; (xiii) comply with the requirements of any other parking and traffic demand management plan to which Tenant may be a party from time to time; (xiii) designate an employee transportation coordinator for the Building; and (xiv) otherwise cooperate with Landlord in encouraging employees to seek alternate modes of transportation.

## 11. Utilities, Services.

(a) **Generally.** Landlord shall provide, subject to the terms of this Section 11, water, electricity, heat, light, power, sewer, and other utilities (including gas and fire sprinklers to the extent the Building is plumbed for such services), refuse and trash collection and janitorial services (collectively, “**Utilities**”). Landlord shall pay, as Operating Expenses or subject to Tenant’s reimbursement obligation below, for all Utilities used on the Premises, all maintenance charges for Utilities, and any storm sewer charges or other similar charges for Utilities imposed by any Governmental Authority or Utility provider, and any taxes, penalties, surcharges or similar charges thereon. Electricity for lights and plugs shall be separately metered or check-metered. Landlord may cause, at Landlord’s expense, any other Utilities to be separately metered or charged directly to Tenant by the provider. Tenant shall pay directly to the Utility provider, prior to delinquency, any separately metered Utilities and services which may be furnished to Tenant or the Premises during the Term. Tenant shall pay, as part of Operating Expenses, its share of all charges for jointly metered Utilities based upon consumption, as reasonably determined by Landlord. No interruption or failure of Utilities, from any cause whatsoever other than Landlord’s willful misconduct, shall result in eviction or constructive eviction of Tenant, termination of this Lease or, except as otherwise provided in the immediately following paragraph, the abatement of Rent.

Notwithstanding anything to the contrary set forth herein, if (i) a stoppage of an Essential Service (as defined below) to the Premises shall occur and such stoppage is due solely to the gross negligence or willful misconduct of Landlord and not due in any part to any act or omission on the part of Tenant or any Tenant Party or any matter beyond Landlord’s reasonable control (any such stoppage of an Essential Service being hereinafter referred to as a “**Service Interruption**”), and (ii) such Service Interruption continues for more than 5 consecutive business days after Landlord shall have received written notice thereof from Tenant, and (iii) as a result of such Service Interruption, the conduct of Tenant’s normal operations in the Premises are materially and adversely affected, then, there shall be an abatement of one day’s Base Rent for each day during which such Service Interruption continues after such 5 business day period; provided, however, that if any part of the Premises is reasonably useable for Tenant’s normal business operations or if Tenant conducts all or any part of its operations in any portion of the Premises notwithstanding such Service Interruption, then the amount of each daily abatement of Base Rent shall only be proportionate to the nature and extent of the interruption of Tenant’s normal operations or ability to use the Premises. The rights granted to Tenant under this paragraph shall be Tenant’s sole and exclusive remedy resulting from a failure of Landlord to provide services, and Landlord shall not otherwise be liable for any loss or damage suffered or sustained by Tenant resulting from any failure or cessation of services. For purposes hereof, the term “**Essential Services**” shall mean the following services: HVAC service, water, sewer and electricity, but in each case only to the extent that Landlord has an obligation to provide same to Tenant under this Lease.

(b) **Generator.** Landlord’s sole obligation for either providing an emergency generator or providing emergency back-up power to Tenant shall be: (i) to provide an emergency generator with not less than the stated capacity of the emergency generator located in the Building as of the Commencement Date, and (ii) to contract with a third party to maintain the emergency generator as per the manufacturer’s standard maintenance guidelines. Except as otherwise provided in the immediately preceding sentence, Landlord shall have no obligation to provide Tenant with an operational emergency generator or back-up power or to supervise, oversee or confirm that the third party maintaining the emergency generator is maintaining the generator as per the manufacturer’s standard guidelines or otherwise. During any period of replacement, repair or maintenance of the emergency generator when the emergency generator is not operational, including any delays thereto due to the inability to obtain parts or replacement equipment, Landlord shall have no obligation to provide Tenant with an alternative back-up generator or generators or alternative sources of back-up power. Tenant expressly acknowledges and agrees that Landlord does not guaranty that such emergency generator will be operational at all times or that emergency power will be

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available to the Premises when needed. In no event shall Landlord be liable to Tenant or any other party for any damages of any type, whether actual or consequential, suffered by Tenant or any such other person in the event that any emergency generator or back-up power or any replacement thereof fails or does not provide sufficient power.

Tenant agrees to provide Landlord with access to Tenant's water and/or energy usage data on a monthly basis, either by providing Tenant's applicable utility login credentials to Landlord's Measurabl online portal, or by another delivery method reasonably agreed to by Landlord and Tenant. The costs and expenses incurred by Landlord in connection with receiving and analyzing such water and/or energy usage data (including, without limitation, as may be required pursuant to applicable Legal Requirements) shall be included as part of Operating Expenses.

(c) **Loading Dock/Freight Elevator.** Tenant may use the common loading dock and freight elevator serving the Building during the Term in common with others entitled thereto at no additional charge. The regular hours of operation of the loading dock and freight elevator are 6:00am to 6:00pm Monday through Friday and 8:00am to 2:00pm on Saturdays, subject to downtime for maintenance and repairs.

(d) **Acid Neutralization System.** Landlord shall provide Tenant with non-exclusive access to the acid neutralization system installed as part of Landlord's Work ("**Acid Neutralization System**") pursuant to the terms and conditions of this Lease. Tenant acknowledges and agrees that the Acid Neutralization System shall be shared with other tenants of the Building. Tenant shall pay its share of ongoing operation costs of the Acid Neutralization System as an Operating Expense, as allocated by Landlord among Tenant and other user tenants on a pro rata basis, with Tenant's share based on the ratio of the rentable square footage of the Premises to the sum of the rentable square footages of the Premises and the premises of all other user tenants. Landlord's sole obligations for providing the Acid Neutralization System, or any acid neutralization system facilities, to Tenant shall be (the "**Acid Neutralization Obligations**") to (i) use reasonable efforts to obtain and maintain the permit required from

the Massachusetts Water Resources Authority for discharge through the Acid Neutralization System (the "**Discharge Permit**"), provided that Tenant reasonably cooperates with Landlord and provides all information and documents reasonably necessary in connection with the Discharge Permit; and (ii) contract with a third party to maintain the Acid Neutralization System as operating as per the manufacturer's standard maintenance guidelines. Notwithstanding anything herein to the contrary, if the Acid Neutralization System must be replaced and the cost thereof is not included in such third party maintenance contract, then, Landlord shall replace the Acid Neutralization System, it being acknowledged, however, that Tenant shall be responsible for its share of all costs incurred in connection therewith as an Operating Expense, as provided in Section 5 above (subject to amortization set forth therein relating to capital improvements).

Tenant shall be solely responsible for the use of the Acid Neutralization System by Tenant and all Tenant Parties or any party other than Landlord or Landlord's contractors, and Tenant shall be jointly and severally responsible for the use of the Acid Neutralization System with the other user tenants. Tenant shall use, and cause other parties under its control or for which it is responsible to use, the Acid Neutralization System in accordance with this Lease and in accordance with all applicable Legal Requirements, the Discharge Permit and any permits and approvals from Governmental Authorities for or applicable to Tenant's use of the Acid Neutralization System. Tenant shall not take any action or make any omission that would result in a violation of the Discharge Permit or any other permit or Legal Requirements applicable to the Acid Neutralization System. Tenant's compliance with applicable permits and Legal Requirements shall include but not be limited to posting signs at all sinks located in the Premises containing applicable notices regarding the use of sink drains for the disposal of chemicals and other Hazardous Materials. Tenant shall maintain a chemical management plan prohibiting the improper discharge or disposal of chemicals. Tenant shall train all laboratory personnel in the Premises on the proper disposal of chemicals and other Hazardous Materials. Landlord reserves the right, at any time and from time to time, to require reasonable limitations and restrictions on discharges by Tenant to the Acid Neutralization System as Landlord may reasonably determine to be necessary for the operation of the Acid Neutralization System. Landlord and its contractors and consultants shall be permitted to perform periodic sampling of all substances regulated under permits applicable to the Acid Neutralization System, including without limitation the discharge permit issued by the Massachusetts Water Resources Authority ("**MWRA**"), or as otherwise deemed appropriate by Landlord in

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its sole discretion. Landlord and its contractors and consultants shall be permitted to perform periodic inspections of the Acid Neutralization System and the discharge points and connections thereto located in the Premises. If requested by Landlord based on conditions pertaining to the Acid Neutralization System, Tenant shall promptly provide updates to its Hazardous Materials List (as defined in Section 30(b), below) to Landlord. Tenant shall promptly notify Landlord of any changes in the flow volume or properties that could impact the operation of the Acid Neutralization System or compliance with applicable permits or Legal Requirements, including without limitation a discharge known or reasonably believed to be non-compliant, changes in Tenant's operations in the Premises and addition of new equipment by Tenant such as cage washers, glass washers or autoclaves.

The scope of the Decommissioning and HazMat Closure Plan (as defined in Section 28 of this Lease) shall include all actions for the proper cleaning, decommissioning and cessation of Tenant's use of the Acid Neutralization System, and all requirements under this Lease for the surrender of the Premises shall also apply to Tenant's cessation of use of the Acid Neutralization System, in each case whether at Lease expiration, termination or prior thereto (but Tenant shall not be required to complete the decommissioning of the Acid Neutralization System if other tenants or occupants will continue to use the same after the expiration or earlier termination of this Lease, nor shall Tenant be responsible for or bear any costs of decommissioning arising from the use of the Acid Neutralization System by any party other than Tenant; it being agreed that if multiple tenants use the Acid Neutralization System, then Landlord shall be responsible for completing the decommissioning thereof, and Tenant shall pay to Landlord within thirty (30) days after invoice therefor Tenant's share of the reasonable, actual costs of decommissioning based on the ratio of the rentable square footage of the Premises to the rentable square footage of the Premises and the premises of all other user tenants). The obligations of Tenant under this Lease with respect to the Acid Neutralization System shall be joint and several with such other tenants as aforesaid,

except in the event that Tenant can prove to Landlord's reasonable satisfaction that neither Tenant nor any Tenant Party caused, contributed to or exacerbated the matter for which Tenant would otherwise be jointly and severally responsible but for this exception. Without in any way limiting the Acid Neutralization Obligations, Landlord shall have no obligation to provide Tenant with operational emergency or back-up acid neutralization facilities or to supervise, oversee or confirm that the third party maintaining the Acid Neutralization System is maintaining such system as per the manufacturer's standard guidelines or otherwise. During any period of replacement, repair or maintenance of the Acid Neutralization System when such system is not operational, including any delays thereto due to the inability to obtain parts or replacement equipment, Landlord shall have no obligation to provide Tenant with an alternative back-up system or facilities. Tenant expressly acknowledges and agrees that Landlord does not guaranty that such Acid Neutralization System will be operational at all times or that such system will be available to the Premises when needed. Without in any way limiting the Acid Neutralization Obligations, in no event shall Landlord be liable to Tenant or any other party for any damages of any type, whether actual or consequential, suffered by Tenant or any such other person in the event that the Acid Neutralization System or back-up system, if any, or any replacement thereof fails or does not operate in a manner that meets Tenant's requirements. For the avoidance of doubt, the foregoing shall not abrogate Landlord's responsibilities under this Lease.

**12. Alterations and Tenant's Property.** Any alterations, additions, or improvements made to the Premises by or on behalf of Tenant (not including the Tenant Improvements which are governed by the Work Letter), including additional locks or bolts of any kind or nature upon any doors or windows in the Premises, but excluding installation, removal or realignment of furniture systems (other than removal of furniture systems owned or paid for by Landlord) not involving any modifications to the structure or connections (other than by ordinary plugs or jacks) to Building Systems (as defined in Section 13) ("**Alterations**") shall be subject to Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion if any such Alteration affects the structure or Building Systems, but which shall otherwise not be unreasonably withheld, conditioned or delayed. Tenant may construct nonstructural, cosmetic Alterations in the Premises that will not affect the operations of any Building Systems, without Landlord's prior approval if the aggregate cost of all such work in any 12 month period does not exceed \$4.00 per rentable square foot of the Premises (excluding paint and floor coverings) (a "**Notice-Only Alteration**"), provided Tenant notifies Landlord in writing of such intended Notice-Only Alteration, and such

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notice shall be accompanied by plans, specifications, work contracts and such other information concerning the nature and cost of the Notice-Only Alteration as may be reasonably requested by Landlord, which notice and accompanying materials shall be delivered to Landlord not less than 15 days in advance of any proposed construction. If Landlord approves any Alterations, Landlord may impose such commercially reasonable conditions on Tenant in connection with the commencement, performance and completion of such Alterations as Landlord may deem appropriate in Landlord's reasonable discretion. Any request for approval shall be in writing, delivered not less than 15 business days in advance of any proposed construction, and accompanied by plans, specifications, bid proposals, work contracts and such other information concerning the nature and cost of the alterations as may be reasonably requested by Landlord, including the identities and mailing addresses of all persons performing work or supplying materials. Any disapproval of plans and specifications for Alterations shall be accompanied by a specific statement of the reason(s) therefor. All architects, consultants, contractors and other persons performing work or supplying materials shall be subject to Landlord's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed. Landlord's right to review plans and specifications and to monitor construction shall be solely for its own benefit, and Landlord shall have no duty to ensure that such plans and specifications or construction comply with applicable Legal Requirements. Tenant shall cause, at its sole cost and expense, all Alterations to comply with insurance requirements and with Legal Requirements and shall implement at its sole cost and expense any alteration or modification required by Legal Requirements as a result of any Alterations. Tenant shall pay to Landlord, as Additional Rent, within 30 days after demand therefor from Landlord, an amount equal to the reasonable third party out-of-pocket costs incurred by Landlord for plan review, coordination, scheduling and supervision with respect to each Alteration. Before Tenant begins any Alteration, Landlord may post on and about the Premises notices of non-responsibility pursuant to applicable law. Tenant shall reimburse Landlord for, and indemnify and hold Landlord harmless from, any expense incurred by Landlord by reason of faulty work done by Tenant or its contractors, delays caused by such work, or inadequate cleanup.

In connection with any Alteration the cost of which is expected to exceed \$5,000,000.00, Landlord may require Tenant to furnish security or make other arrangements satisfactory to Landlord to assure payment for the completion of all Alterations work free and clear of liens. Tenant shall, with respect to all Alterations, shall provide (and cause each contractor or subcontractor to provide) certificates of insurance for workers' compensation and other coverage in amounts and from an insurance company satisfactory to Landlord protecting Landlord against liability for personal injury or property damage during construction. Upon completion of any Alterations, Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and subcontractors who did the work and final lien waivers from all such contractors and subcontractors; and (ii) "as built" plans for any such Alteration. Notwithstanding anything to the contrary set forth herein, in no event shall Tenant be required to provide Landlord with a payment or performance bond with respect to the Tenant Improvements.

Other than (i) the items, if any, listed on **Exhibit F** attached hereto, (ii) any items agreed by Landlord in writing to be included on **Exhibit F** in the future, and (iii) any trade fixtures, machinery, equipment and other personal property not paid for out of the TI Fund (as defined in the Work Letter) which may be removed without material damage to the Premises, which damage shall be repaired (including capping or terminating utility hook-ups behind walls) by Tenant during the Term (collectively, "**Tenant's Property**"), all property of any kind paid for with the TI Fund, all Alterations, real property fixtures, built-in machinery and equipment, built-in casework and cabinets and other similar additions and improvements built into the Premises so as to become an integral part of the Premises, such as fume hoods which penetrate the roof or plenum area, built-in cold rooms, built-in warm rooms, walk-in cold rooms, walk-in warm rooms, deionized water systems, glass washing equipment, autoclaves, chillers, built-in plumbing, electrical and mechanical equipment and systems, and any power generator and transfer switch (collectively, "**Installations**") shall be and shall remain the property of Landlord during the Term and following the expiration or earlier termination of the Term, shall not be removed by Tenant at any time during the Term and shall remain upon and be surrendered with the Premises as a part thereof in accordance with Section 28 following the expiration or earlier termination of this Lease; provided, however, that Landlord shall, at the time its approval of such Installation is requested, or at the time it receives notice of a Notice-Only Alteration, notify Tenant if it has elected to cause Tenant to remove such Installation upon the expiration or earlier termination of this Lease, except that Landlord shall not require removal of customary office cabling unless otherwise required by Legal Requirements. If Landlord so elects, Tenant shall remove such Installation upon the expiration or

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earlier termination of this Lease and restore any damage caused by or occasioned as a result of such removal, including, when removing any of Tenant's Property which was plumbed, wired or otherwise connected to any of the Building Systems, capping off all such connections behind the walls of the Premises and repairing any holes. During any such restoration period, Tenant shall pay Rent to Landlord as provided herein as if said space were otherwise occupied by Tenant.

Notwithstanding anything to the contrary contained herein, Tenant shall not be required to remove or restore any Tenant Improvements that are generic in nature and reusable by future tenants of the Premises for laboratory/life science purposes, as reasonably determined by Landlord at the time of Landlord's approval of the Space Plans (as defined in the Work Letter) (and with respect to any Changes (as such term is defined in the Work Letter), at the time Landlord's approval of any such Change), nor shall Tenant have the right to remove such Tenant Improvements at any time during the Term, other than in accordance with the terms of this Section 12. Notwithstanding anything to the contrary contained in this Lease or the Work Letter, Tenant may during the Term, replace components of furniture, fixtures and equipment paid for out of the Additional Tenant Improvement Allowance with "like-kind" furniture, fixtures and equipment reasonably acceptable to Landlord, which replacement components shall become Landlord's property at remain in the Premises at the expiration or earlier termination of the Term.

**13. Landlord's Repairs.** Landlord, as an Operating Expense (except to the extent the cost thereof is excluded from Operating Expenses pursuant to Section 5 hereof), shall maintain, or cause to be maintained, the roof and all of the structural, exterior, parking and other Common Areas of the Building and Project, and all building systems serving the Premises and other portions of the Project including, without limitation, HVAC, plumbing, fire sprinklers, elevators ("**Building Systems**"), in good operating order and repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of Tenant's assignees, sublessees, licensees, agents, servants, employees, invitees and contractors (or any of Tenant's assignees, sublessees and/or licensees respective agents, servants, employees, invitees and contractors) (collectively, "**Tenant Parties**") excluded. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant's sole cost and expense. Landlord reserves the right to stop Building Systems services when necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 48 hours advance notice of any planned stoppage of Building Systems services for routine maintenance, repairs, alterations or improvements. Landlord shall use reasonable efforts to minimize interference with Tenant's operations in the Premises during such planned stoppages of Building Systems and shall use reasonable efforts to coordinate such planned stoppages in advance (except in the case of an emergency) with Tenant. Tenant shall promptly give Landlord written notice of any repair required by Landlord pursuant to this Section, after which Landlord shall make a commercially reasonable effort to effect such repair. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant's written notice of the need for such repairs or maintenance. Tenant waives its rights under any state or local law to terminate this Lease or to make such repairs at Landlord's expense and agrees that the parties' respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by Section 18.

**14. Tenant's Repairs.** Subject to Section 13 hereof, Tenant, at its expense, shall repair, replace and maintain, in the condition the same are in on the Commencement Date (reasonable wear and tear and damage by casualty excepted), all portions of the Premises, including, without limitation, entries, doors, ceilings, interior windows, interior walls, and the interior side of demising walls. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant written notice of such failure. If Tenant fails to commence cure of such failure within 10 days of Landlord's written notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed by Tenant within 30 days after Landlord's written demand therefor; provided, however, that if such failure by Tenant creates or could reasonably be expected to create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to recover the costs of such

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cure from Tenant. Subject to Sections 17 and 18, Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repair that benefits only the Premises.

**15. Mechanic's Liens.** Tenant shall discharge, by bond or otherwise, any mechanic's lien filed against the Premises or against the Building, Property or Project for work claimed to have been done for, or materials claimed to have been furnished to, Tenant within 10 business days after Tenant receives written notice of the filing thereof, at Tenant's sole cost and shall otherwise keep the Premises and the Building, Property and Project free from any liens arising out of work performed, materials furnished or obligations incurred by Tenant. Should Tenant fail to discharge any lien described herein, Landlord shall have the right, but not the obligation, to pay such claim or post a bond or otherwise provide security to eliminate the lien as a claim against title to the Building, Property or Project and the cost thereof shall be immediately due from Tenant as Additional Rent within 5 days of written demand therefor. If Tenant shall lease or finance the acquisition of office equipment, furnishings, or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code Financing Statement filed as a matter of public record by any lessor or creditor of Tenant will upon its face or by exhibit thereto indicate that such Financing Statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Building or Project be furnished on the statement without qualifying language as to applicability of the lien only to removable personal property, located in an identified suite held by Tenant.

**16. Indemnification.** Subject to the penultimate paragraph of Section 17, Tenant hereby indemnifies and agrees to defend, save and hold Landlord, its officers, directors, employees, managers, agents, sub-agents, constituent entities and lease signatories (collectively, "**Landlord Indemnified Parties**") and Holders of Mortgages (each as defined in Section 27 below) as to which Tenant has been given notice harmless from and against any and all Claims for injury or death to persons or damage to property occurring within or about the Premises, arising directly or indirectly out of the use or occupancy of the Premises or the Project by Tenant or any Tenant Parties (including, without limitation, any act, omission or neglect by Tenant or any Tenant Parties in or about the Premises or at the Project) or a breach or default by Tenant in the performance of any of its obligations hereunder, except to the extent caused by the willful misconduct or negligence of Landlord Indemnified Parties. Landlord Indemnified Parties shall not be liable to Tenant for, and Tenant assumes all risk of damage to, personal property (including, without limitation, loss of records kept within the Premises). Tenant further hereby irrevocably waives any and all Claims for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property (including, without limitation, any loss of records). Landlord Indemnified Parties shall not be liable for any damages arising from any act, omission or neglect of any tenant in the Project or of any other third party.

Subject to all of the other provisions of this Lease including, without limitation, the waivers provided in Sections 17 and 36, Landlord hereby indemnifies and agrees to defend, save and hold Tenant harmless from and against any and all third party Claims for injury or death to persons or damage to property occurring within the Common Areas of the Project caused by Landlord's willful misconduct or negligence, except to the extent caused by the willful misconduct or negligence of Tenant or its employees or agents.

**17. Insurance.** Landlord shall maintain all risk property and, if applicable, sprinkler damage insurance covering the full replacement cost of the Building. Landlord shall further procure and maintain commercial general liability insurance with a single loss limit of not less than \$2,000,000 for bodily injury and property damage with respect to the Project. Landlord may, but is not obligated to, maintain such other insurance and additional coverages as it may deem necessary, including, but not limited to, flood, environmental hazard and earthquake, loss or failure of building equipment, errors and omissions, rental loss during the period of repair or rebuilding, workers' compensation insurance and fidelity bonds for employees employed to perform services and insurance for any improvements installed by Tenant or which are in addition to the standard improvements customarily furnished by Landlord without regard to whether or not such are made a part of the Project. All such insurance shall be included as part of the Operating Expenses. The Building and Property may be included in a blanket policy (in which case the cost of such insurance allocable to the Building and Property will be determined by Landlord based upon the insurer's

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cost calculations). Tenant shall also reimburse Landlord for any increased premiums or additional insurance which Landlord reasonably deems necessary as a result of Tenant's particular use of the Premises.

Tenant, at its sole cost and expense, shall maintain during the Term: all risk property insurance with business interruption and extra expense coverage, covering the full replacement cost of all property and improvements installed or placed in the Premises by Tenant at Tenant's expense; workers' compensation insurance with no less than the minimum limits required by law; employer's liability insurance with employers liability limits of \$1,000,000 bodily injury by accident – each accident,

\$1,000,000 bodily injury by disease – policy limit, and \$1,000,000 bodily injury by disease – each employee; and commercial general liability insurance, with a minimum limit of not less than \$5,000,000 per occurrence for bodily injury and property damage with respect to the Premises (the "**Umbrella Policy**"). The commercial general liability insurance maintained by Tenant shall name Alexandria Real Estate Equities, Inc., and Landlord, its officers, directors, employees, managers, agents, sub-agents, constituent entities and lease signatories (collectively, "**Landlord Insured Parties**"), as additional insureds; insure on an occurrence and not a claims-made basis; be issued by insurance companies which have a rating of not less than policyholder rating of A and financial category rating of at least Class X in "Best's Insurance Guide"; not contain a hostile fire exclusion; contain a contractual liability endorsement; and provide primary coverage to Landlord Insured Parties (any policy issued to Landlord Insured Parties providing duplicate or similar coverage shall be deemed excess over Tenant's policies, regardless of limits). Tenant shall (i) provide Landlord with 30 days advance written notice of cancellation of such commercial general liability policy, and (ii) request Tenant's insurer to endeavor to provide advance written notice to Landlord of cancellation of such commercial general liability policy. Copies of such policies (if requested by Landlord), or certificates of insurance showing the limits of coverage required hereunder and showing Landlord as an additional insured, along with reasonable evidence of the payment of premiums for the applicable period, shall be delivered to Landlord by Tenant prior to (i) the earlier to occur of (x) the Commencement Date, or (y) the date that Tenant accesses the Premises under this Lease, and (ii) each renewal of said insurance. Tenant's policy may be a "blanket policy" with an aggregate per location endorsement which specifically provides that the amount of insurance shall not be prejudiced by other losses covered by the policy. Tenant shall, prior to the expiration of such policies, furnish Landlord with renewal certificates.

In each instance where insurance is to name Landlord as an additional insured, Tenant shall upon written request of Landlord also designate and furnish certificates so evidencing Landlord as additional insured to: (i) any lender of Landlord holding a security interest in the Building, Property or Project or any portion thereof and any servicer in connection therewith, (ii) the landlord under any lease wherein Landlord is tenant of the real property on which the Building, Property or Project is located, if the interest of Landlord is or shall become that of a tenant under a ground or other underlying lease rather than that of a fee owner, and/or (iii) any management company retained by Landlord to manage the Project.

The property insurance obtained by Landlord and Tenant shall include a waiver of subrogation by the insurers and all rights based upon an assignment from its insured, against Landlord or Tenant, and their respective officers, directors, employees, managers, agents, invitees and contractors ("**Related Parties**"), in connection with any loss or damage thereby insured against. Notwithstanding anything in this Lease to the contrary, neither party nor its respective Related Parties shall be liable to the other for loss or damage caused by any risk insured against (or required to be insured against pursuant to this Lease) under property insurance required to be maintained hereunder, and each party waives any claims against the other party, and its respective Related Parties, for such loss or damage. The failure of a party to insure its property shall not void this waiver. Landlord and its respective Related Parties shall not be liable for, and Tenant hereby waives all claims against such parties for, business interruption and losses occasioned thereby sustained by Tenant or any person claiming through Tenant resulting from any accident or occurrence in or upon the Premises, Building, Property or Project from any cause whatsoever. If the foregoing waivers shall contravene any law with respect to exculpatory agreements, the liability of Landlord or Tenant shall be deemed not released but shall be secondary to the other's insurer.

Landlord may require insurance policy limits to be raised to conform with requirements of Landlord's lender and/or to bring coverage limits to levels then being generally required of new tenants within the Project; provided, however, that the increased amount of coverage is consistent with coverage amounts then being required by institutional owners of similar projects with tenants occupying similar size premises

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in the geographical area in which the Project is located.

**18. Restoration.** If, at any time during the Term, the Building or the Premises are damaged or destroyed by a fire or other insured casualty, Landlord shall notify Tenant within 60 days after discovery of such damage as to the amount of time Landlord reasonably estimates it will take to restore the Building or the Premises, as applicable (the “**Restoration Period**”). If the Restoration Period is estimated to exceed 12 months (the “**Maximum Restoration Period**”), Landlord may, in such notice, elect to terminate this Lease as of the date that is 75 days after the date of discovery of such damage or destruction; provided, however, that notwithstanding Landlord’s election to restore, Tenant may elect to terminate this Lease by written notice to Landlord delivered within 10 business days of receipt of a notice from Landlord estimating a Restoration Period for the Premises longer than the Maximum Restoration Period. Unless either Landlord or Tenant so elects to terminate this Lease, Landlord shall, subject to receipt of sufficient insurance proceeds (with any deductible to be treated as a current Operating Expense), promptly restore the Premises (excluding the improvements installed by Tenant or by Landlord and paid for by Tenant except to the extent to which Landlord receives insurance proceeds for the restoration of improvements from the insurance required to be maintained by Landlord under Section 17, in which case such improvements shall be included as part of Landlord’s restoration), subject to delays arising from the collection of insurance proceeds, from Force Majeure events or as needed to obtain any license, clearance or other authorization of any kind required to enter into and restore the Premises issued by any Governmental Authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials (as defined in Section 30) in, on or about the Premises (collectively referred to herein as “**Hazardous Materials Clearances**”); provided, however, that if repair or restoration of the Premises is not substantially complete as of the end of the Maximum Restoration Period or, if longer, the Restoration Period, Landlord may, in its sole and absolute discretion, elect not to proceed with such repair and restoration, or Tenant may by written notice to Landlord delivered within 10 business days of the expiration of the Maximum Restoration Period or, if longer, the Restoration Period, elect to terminate this Lease, in either of which events Landlord shall be relieved of its obligation to make such repairs or restoration and this Lease shall terminate as of the date that is 75 days after the later of: (i) discovery of such damage or destruction, or (ii) the date all required Hazardous Materials Clearances are obtained, but Landlord shall retain any Rent paid and the right to any Rent payable by Tenant prior to such election by Landlord or Tenant.

Tenant, at its expense, following the date that Landlord makes the Premises available to Tenant for Tenant’s repairs or restoration, shall promptly perform, subject to delays arising from the collection of insurance proceeds, from Force Majeure (as defined in Section 34) events or to obtain Hazardous Materials Clearances, all repairs or restoration not required to be done by Landlord and shall promptly reenter the Premises and commence doing business in accordance with this Lease. Notwithstanding the foregoing, Landlord or Tenant may terminate this Lease if the Premises are damaged during the last year of the Term and Landlord reasonably estimates that it will take more than 2 months to repair such damage; provided, however, that such notice is delivered within 10 business days after the date that Landlord delivers notice to Tenant of the estimated Restoration Period. Notwithstanding anything to the contrary contained in this Lease, Landlord shall also have the right to terminate this Lease if insurance proceeds are not available for such restoration, provided that such unavailability of insurance proceeds is not the result of Landlord’s failure to maintain the insurance policies required to be maintained by Landlord under Section 17. Rent shall be abated from the date all required Hazardous Materials Clearances are obtained until the Premises are repaired and restored, in the proportion which the area of the Premises, if any, which is not usable by Tenant bears to the total area of the Premises, unless Landlord provides Tenant with other space during the period of repair that is suitable for the temporary conduct of Tenant’s business. In the event that no Hazardous Materials Clearances are required to be obtained with respect to such fire or other casualty, the rent abatement shall commence as of the date of discovery of the damage or destruction. Such abatement shall be the sole remedy of Tenant, and except as provided in this Section 18, Tenant waives any right to terminate the Lease by reason of damage or casualty loss.

The provisions of this Lease, including this Section 18, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, or any other portion of the Building, Property or Project, and any statute or regulation which is now or may hereafter be in effect shall have no application to this Lease or any damage or destruction to all or any part

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of the Premises or any other portion of the Building, Property or Project, the parties hereto expressly agreeing that this Section 18 sets forth their entire understanding and agreement with respect to such matters.

**19. Condemnation.** If the whole or any material part of the Premises, Building or Property is taken for any public or quasi-public use under governmental law, ordinance, or regulation, or by right of eminent domain, or by private purchase in lieu thereof (a “**Taking**” or “**Taken**”) or if there is no access to the Premises (other than on a temporary basis) and the Taking would in Landlord’s reasonable judgment materially interfere with or impair Landlord’s ownership or operation of the Building or Property, or would in the reasonable judgment of Landlord and Tenant either prevent or materially interfere with Tenant’s use of the Premises (as resolved, if the parties are unable to agree, by arbitration by a single arbitrator with the qualifications and experience appropriate to resolve the matter and appointed pursuant to and acting in accordance with the rules of the American Arbitration Association), then upon written notice by Landlord or Tenant to the other this Lease shall terminate and Rent shall be apportioned as of said date. If part of the Premises shall be Taken, and this Lease is not terminated as provided above, Landlord shall promptly restore the Premises and the Building and Property as nearly as is commercially reasonable under the circumstances to their condition prior to such partial Taking and the rentable square footage of the Building, the rentable square footage of the Premises, Tenant’s Share of Operating Expenses, and the Rent payable hereunder during the unexpired Term shall be reduced to such extent as may be fair and reasonable under the circumstances. Upon any such Taking, Landlord shall be entitled to receive the entire price or award from any such Taking without any payment to Tenant, and Tenant hereby assigns to Landlord Tenant’s interest, if any, in such award. Tenant shall have the right, to the extent that same shall not diminish Landlord’s award, to make a separate claim against the condemning authority (but not Landlord) for such compensation as may be separately awarded or recoverable by Tenant for moving expenses and damage to Tenant’s trade fixtures, if a separate award for such items is made to Tenant. Tenant hereby waives any and all rights it might otherwise have pursuant to any provision of state law to terminate this Lease upon a partial Taking of the Premises, Building, Property or Project.

**20. Events of Default.** Each of the following events shall be a default (“**Default**”) by Tenant under this Lease:

(a) **Payment Defaults.** Tenant shall fail to pay any installment of Rent or any other payment hereunder when due; provided, however, that Landlord will give Tenant written notice and an opportunity to cure any failure to pay Rent within 5 business days of any such written notice not more than twice in any 12 month period and Tenant agrees that such written notice shall be in lieu of and not in addition to, or shall be deemed to be, any notice required by law.

(b) **Insurance.** Any insurance required to be maintained by Tenant pursuant to this Lease shall be canceled or terminated or shall expire or shall be reduced or materially changed in a manner so that it does not comply with the terms of this Lease, or Landlord shall receive a notice of nonrenewal of any such insurance and Tenant shall fail to obtain replacement insurance before the expiration of the current coverage.

(c) **Abandonment.** Tenant shall abandon the Premises, provided that Tenant shall not be deemed to have abandoned the Premises if (i) Tenant provides Landlord with reasonable advance notice prior to vacating and, at the time of vacating the Premises, Tenant has completed Tenant’s obligations with respect to the Decommissioning and HazMat Closure Plan in compliance with Section 28, (ii) Tenant has made reasonable arrangements for the security of the Premises for the balance of the Term, and (iii) Tenant continues during the balance of the Term to satisfy all of its obligations under the Lease as they come due, including without limitation the obligation to pay Rent.

(d) **Improper Transfer.** Tenant shall assign, sublease or otherwise transfer or attempt to transfer all or any portion of Tenant’s interest in this Lease or the Premises except as expressly permitted herein, or Tenant’s interest in this Lease shall be attached, executed upon, or otherwise judicially seized and such action is not released within 90 days of the action.

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(e) **Liens.** Tenant shall fail to discharge or otherwise obtain the release of any lien placed upon the Premises in violation of this Lease within the time period required pursuant to Section 15 of this Lease.

(f) **Insolvency Events.** Tenant or any guarantor or surety of Tenant's obligations hereunder shall: (A) make a general assignment for the benefit of creditors; (B) commence any case, proceeding or other action seeking to have an order for relief entered on its behalf as a debtor or to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, liquidation, dissolution or composition of it or its debts or seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or of any substantial part of its property (collectively a "**Proceeding for Relief**"); (C) become the subject of any Proceeding for Relief which is not dismissed within 90 days of its filing or entry; or (D) die or suffer a legal disability (if Tenant, guarantor, or surety is an individual) or be dissolved or otherwise fail to maintain its legal existence (if Tenant, guarantor or surety is a corporation, partnership or other entity).

(g) **Estoppel Certificate or Subordination Agreement.** Tenant fails to execute any document required from Tenant under Sections 23 or 27 within 5 days after a second written notice requesting such document.

(h) **Other Defaults.** Tenant shall fail to comply with any provision of this Lease other than those specifically referred to in this Section 20, and, except as otherwise expressly provided herein, such failure shall continue for a period of 30 days after written notice thereof from Landlord to Tenant.

Any notice given under Section 20(h) hereof shall: (i) specify the alleged default, (ii) demand that Tenant cure such default, (iii) be in lieu of, and not in addition to, or shall be deemed to be, any notice required under any provision of applicable law, and (iv) not be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice; provided that if the nature of Tenant's default pursuant to Section 20(h) is such that it cannot be cured by the payment of money and reasonably requires more than 30 days to cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said 30 day period and thereafter diligently prosecutes the same to completion; provided, however, that such cure shall be completed no later than 90 days from the date of Landlord's notice.

## 21. Landlord's Remedies.

(a) **Payment By Landlord; Interest.** Upon a Default by Tenant hereunder, Landlord may, without waiving or releasing any obligation of Tenant hereunder, make such payment or perform such act. All sums so paid or incurred by Landlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to 12% per annum or the highest rate permitted by law (the "**Default Rate**"), whichever is less, shall be payable to Landlord on demand as Additional Rent. Nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant's Default hereunder.

(b) **Late Payment Rent.** Late payment by Tenant to Landlord of Rent and other sums due will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges which may be imposed on Landlord under any Mortgage covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within 5 days after the date such payment is due, Tenant shall pay to Landlord an additional sum equal to 6% of the overdue Rent as a late charge. Notwithstanding the foregoing, before assessing a late charge the first time in any calendar year, Landlord shall provide Tenant written notice of the delinquency and will waive the right if Tenant pays such delinquency within 5 days thereafter. The parties agree that this late charge represents a fair and reasonable estimate of the costs Landlord will incur by reason of late payment by Tenant. In addition to the late charge, Rent not paid when due shall bear interest at the Default Rate from the 5th day after the date due until paid.

(c) **Remedies.** Upon the occurrence of a Default, Landlord, at its option, without further notice or demand to Tenant, shall have in addition to all other rights and remedies provided in this Lease, at law or in equity, the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever (except as otherwise

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expressly provided in Section 21(c)(v) with respect to Landlord's Lump Sum Election). No cure in whole or in part of such Default by Tenant after Landlord has taken any action beyond giving Tenant notice of such Default to pursue any remedy provided for herein (including retaining counsel to file an action or otherwise pursue any remedies) shall in any way affect Landlord's right to pursue such remedy or any other remedy provided Landlord herein or under law or in equity, unless Landlord, in its sole discretion, elects to waive such Default.

(i) This Lease and the Term and estate hereby granted are subject to the limitation that whenever a Default shall have happened and be continuing, Landlord shall have the right, at its election, then or thereafter while any such Default shall continue and notwithstanding the fact that Landlord may have some other remedy hereunder or at law or in equity, to give Tenant written notice of Landlord's intention to terminate this Lease on a date specified in such notice, which date shall be not less than 5 days after the giving of such notice, and upon the date so specified, this Lease and the estate hereby granted shall expire and terminate with the same force and effect as if the date specified in such notice were the date hereinbefore fixed for the expiration of this Lease, and all rights of Tenant hereunder shall expire and terminate, and Tenant shall be liable as hereinafter in this Section 21(c) provided. If any such notice is given, Landlord shall have, on such date so specified, the right of re-entry and possession of the Premises and the right to remove all persons and property therefrom and to store such property in a warehouse or elsewhere at the risk and expense, and for the account, of Tenant. Should Landlord elect to re-enter as herein provided or should Landlord take possession pursuant to legal proceedings or pursuant to any notice provided for by law, Landlord may, subject to Section 21(c)(ii), from time to time re-let the Premises or any part thereof for such term or terms and at such rental or rentals and upon such terms and conditions as Landlord may deem advisable, with the right to make commercially reasonable alterations in and repairs to the Premises.

(ii) Landlord shall be deemed to have satisfied any obligation to mitigate its damages by hiring an experienced commercial real estate broker to market the Premises and directing such broker to advertise and show the Premises to prospective tenants.

(iii) In the event of any termination of this Lease as in this Section 21 provided or as required or permitted by law or in equity, Tenant shall forthwith quit and surrender the Premises to Landlord, and Landlord may, without further notice, enter upon, re-enter, possess and repossess the same by summary proceedings, ejectment or otherwise, and again have, repossess and enjoy the same free of any rights of Tenant, and in any such event Tenant and no person claiming through or under Tenant by virtue of any law or an order of any court shall be entitled to possession or to remain in possession of the Premises.

(iv) If this Lease is terminated or if Landlord shall re-enter the Premises as aforesaid, or in the event of the termination of this Lease, or of re-entry, by or under any proceeding or action or any provision of law by reason of a Default by Tenant, Tenant covenants and agrees forthwith to pay and be liable for, on the days originally fixed in this Lease for the payment thereof, amounts equal to the installments of Base Rent and all Additional Rent as they would, under the terms of this Lease become due if this Lease had not been terminated or if Landlord had not entered or re-entered, as aforesaid, and whether the Premises be relet or remain vacant, in whole or in part, or for a period less than the remainder of the Term, or for the whole thereof, but in the event that the Premises be relet by Landlord, Tenant shall be entitled to a credit in the net amount of rent and other charges received by Landlord in reletting, after deduction of all of Landlord's expenses incurred in reletting the Premises (including, without limitation, tenant improvement, demising and remodeling costs, brokerage fees and the like), and in collecting the rent in connection therewith, in the following manner: Amounts received by Landlord after reletting, if any, shall first be applied against such Landlord's expenses, until the same are recovered, and until such recovery, Tenant shall pay, as of each day when a payment would fall due under this Lease, the amount which Tenant is obligated to pay under the terms of this Lease (Tenant's liability prior to any such reletting and such recovery by Landlord no in any way to be diminished as a result of the fact that such reletting might be for a rent higher than the rent provided for in this Lease); when and if such expenses have been completely recovered by Landlord, the amounts received from reletting by

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Landlord as have not previously been applied shall be credited against Tenant's obligations as of each day when a payment would fall due under this Lease, and only the net amount thereof shall be payable by Tenant. Further, Tenant shall not be entitled to any credit of any kind for any period after the date when the Term of this Lease is scheduled to expire according to its terms.

Actions, proceedings or suits for the recovery of damages, whether liquidated or other damages, under this Lease, or any installments thereof, may be brought by Landlord from time to time at its election, and nothing contained herein shall be deemed to require Landlord to postpone suit until the date when the Term of this Lease would have expired if it had not been terminated hereunder.

(v) In addition, Landlord, at its election, notwithstanding any other provision of this Lease, by written notice to Tenant (the "**Lump Sum Election**"), shall be entitled to recover from Tenant, as and for liquidated damages, at any time following any termination of this Lease, a lump sum payment representing, at the time of Landlord's written notice of its Lump Sum Election, the sum of:

(A) the then present value (calculated in accordance with accepted financial practice using as the discount rate the yield to maturity on United States Treasury Notes as set forth below) of the amount of unpaid Base Rent and Additional Rent that would have been payable pursuant to this Lease for the remainder of the Term following Landlord's Lump Sum Election if this Lease had not been terminated, and

(B) all other damages and expenses (including attorneys' fees and expenses), if any, which Landlord shall have sustained by reason of the breach of any provision of this Lease; less

(C) the then present value (calculated in accordance with accepted financial practice using as the discount rate the yield to maturity on United States Treasury Notes as set forth below) of the aggregate net fair market rent plus additional charges payable for the Premises (if less than the then present value of Base Rent and Additional Rent that would have been payable pursuant to this Lease) for the remainder of the Term following Landlord's Lump Sum Election, calculated as of the date of Landlord's Lump Sum Election, and taking into account reasonable estimates of the future costs to relet any then vacant portions of the Premises (except to the extent that Tenant has actually paid such costs pursuant to this Section 21) in order to calculate the net rental revenue that Landlord may expect to obtain for the Premises for the balance of the Term.

Landlord's recovery under its Lump Sum Election shall be in addition to Tenant's obligations to pay Base Rent and Additional Rent due and costs incurred prior to the date of Landlord's Lump Sum Election, and in lieu of any Base Rent and Additional Rent which would otherwise have been due under this Section from and after the date of Landlord's Lump Sum Election. The yield to maturity on United States Treasury Notes having a maturity date that is nearest the date that would have been the last day of the Term of this Lease, as reported in the Wall Street Journal or a comparable publication if it ceases to publish such yields, shall be used in calculating present values for purposes of Landlord's Lump Sum Election. For the purposes of this Section, if Landlord makes the Lump Sum Election to recover liquidated damages in accordance with this Section, the total Additional Rent shall be computed based upon Landlord's reasonable estimate of Tenant's Share of Operating Expenses and other Additional Rent for each 12-month period in what would have been the remainder of the Term of this Lease and any part thereof at the end of such remainder of the Term, but in no event less than the amounts therefor payable for the twelve (12) calendar months (or if less than twelve (12) calendar months have elapsed since the date hereof, the partial year) immediately preceding the date of Landlord's Lump Sum Election. Amounts of Tenant's Share of Operating Expenses and any other Additional Rent for any partial year at the beginning of the Term or at the end of what would have been the remainder of the Term shall be prorated.

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(vi) Nothing herein contained shall limit or prejudice the right of Landlord, in any bankruptcy or insolvency proceeding, to prove for and obtain as liquidated damages by reason of such termination an amount equal to the maximum allowed by any bankruptcy or insolvency proceedings, or to prove for and obtain as liquidated damages by reason of such termination, an amount equal to the maximum allowed by any statute or rule of law, whether such amount shall be greater or less than the excess referred to above.

(vii) Nothing in this Section 21 shall be deemed to affect the right of either party to indemnifications pursuant to this Lease.

(viii) If Landlord terminates this Lease upon the occurrence of a Default, Tenant will quit and surrender the Premises to Landlord or its agents, and Landlord may, without further notice, enter upon, re-enter and repossess the Premises by summary proceedings, ejectment or otherwise. The words "enter", "re-enter", and "re-entry" are not restricted to their technical legal meanings.

(ix) If either party shall be in default in the observance or performance of any provision of this Lease, and an action shall be brought for the enforcement thereof in which it shall be determined that such party was in default, the party in default shall pay to the other party all reasonable, out of pocket fees, costs and other expenses which may become payable as a result thereof or in connection therewith, including reasonable attorneys' fees and expenses.

(x) If default by Tenant shall occur in the keeping, observance or performance of any covenant, agreement, term, provision or condition herein contained, Landlord, without thereby waiving such default, may perform the same for the account and at the expense of Tenant (a) immediately or at any time thereafter and with only such notice, if any, as may be practicable under the circumstances in the case of an emergency or in case such default will result in a violation of any legal or insurance requirements, or in the imposition of any lien against all or any portion of the Premises or the Project not discharged, released or bonded over to Landlord's satisfaction by Tenant within the time period required pursuant to Section 15 of this Lease, and

(b) in any other case if such default continues after any applicable notice and cure period provided in Section 20. All reasonable costs and expenses incurred by Landlord in connection with any such performance by it for the account of Tenant and also all reasonable costs and expenses, including attorneys' fees and disbursements incurred by Landlord in any action or proceeding (including any summary dispossession proceeding) brought by Landlord to enforce any obligation of Tenant under this Lease and/or right of Landlord in or to the Premises, shall be paid by Tenant to Landlord within 10 days after demand.

(xi) Independent of the exercise of any other remedy of Landlord hereunder or under applicable law, Landlord may conduct an environmental test of the Premises as generally described in Section 30(d).

(xii) In the event that Tenant is in breach or Default under this Lease, whether or not Landlord exercises its right to terminate or any other remedy, Tenant shall reimburse Landlord within 10 days of demand for any out of pocket costs and expenses that Landlord may incur in connection with any such breach or Default, as provided in this Section 21(c). Such costs shall include reasonable legal fees and costs incurred for the negotiation of a settlement, enforcement of rights or otherwise. Tenant shall also indemnify Landlord against and hold Landlord harmless from all costs, expenses, demands and liability, including without limitation, reasonable legal fees and costs Landlord shall incur if Landlord shall become or be made a party to any claim or action instituted by Tenant against any third party, by any third party against Tenant or by or against any person holding any interest under or using the Premises by license of or agreement with Tenant. Except as otherwise provided in this Section 21, no right or remedy herein conferred upon or reserved to Landlord is intended to be exclusive of any other right or remedy, and every right and remedy shall be cumulative and in addition to any other legal or equitable right or remedy given hereunder, or now or hereafter existing. No waiver of any provision of this Lease shall be deemed to have been made unless expressly so made in writing expressly waiving such provision. Landlord

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shall be entitled, to the extent permitted by law, to seek injunctive relief in case of the violation, or attempted or threatened violation, of any provision of this Lease, or to seek a decree compelling observance or performance of any provision of this Lease, or to seek any other legal or equitable remedy. Notwithstanding any contrary provision of this Lease, neither Tenant nor Landlord shall be liable to the other for any indirect, special or consequential damages; provided, however, that this sentence shall not apply to Landlord's damages (x) as expressly provided for in Section 8, and/or (y) in connection with Tenant's obligations as more fully set forth in Section 30.

## 22. Assignment and Subletting.

(a) **General Prohibition.** Without Landlord's prior written consent (which shall be given or withheld pursuant to the terms of Section 22(b) below) subject to and on the conditions described in this Section 22, Tenant shall not, directly or indirectly, voluntarily or by operation of law, assign this Lease or sublease the Premises or any part thereof or mortgage, pledge, or hypothecate its leasehold interest or grant any concession or license within the Premises, and any attempt to do any of the foregoing shall be void and of no effect. If Tenant is a corporation, partnership or limited liability company, the shares or other ownership interests thereof which are not actively traded upon a stock exchange or in the over-the-counter market, a transfer or series of transfers whereby 50% or more of the issued and outstanding shares or other ownership interests of such corporation are, or voting control is, transferred (but excepting transfers upon deaths of individual owners) from a person or persons or entity or entities which were owners thereof at time of execution of this Lease to persons or entities who were not owners of shares or other ownership interests of the corporation, partnership or limited liability company at time of execution of this Lease, shall be deemed an assignment of this Lease requiring the consent of Landlord as provided in this Section 22. Notwithstanding the foregoing, Tenant shall have the right to obtain financing from institutional investors (including venture capital funding and corporate partners) or undergo a public offering which results in a change in control of Tenant without such change of control constituting an assignment under this Section 22 requiring Landlord consent, provided that (i) Tenant notifies Landlord in writing of the financing at least 5 business days prior to the closing of the financing, and (ii) provided that in no event shall such financing result in a change in use of the Premises from the use contemplated by Tenant at the commencement of the Term.

(b) **Permitted Transfers.** If Tenant desires to assign, sublease, hypothecate or otherwise transfer this Lease or sublet the Premises, other than pursuant to a Permitted Assignment or Shared Space Arrangement (each as defined below) then at least 15 days, but not more than 45 business days, before the date Tenant desires the assignment or sublease to be effective (the "**Assignment Date**"), Tenant shall give Landlord a notice (the "**Assignment Notice**") containing such information about the proposed assignee or sublessee, including the proposed use of the Premises and any Hazardous Materials proposed to be used, stored handled, treated, generated in or released or disposed of from the Premises, the Assignment Date, any relationship between Tenant and the proposed assignee or sublessee, and all material terms and conditions of the proposed assignment or sublease, including a copy of any proposed assignment or sublease in its then-current form, and such other information as Landlord may deem reasonably necessary or appropriate to its consideration whether to grant its consent. Landlord may, by giving written notice to Tenant within 15 days after receipt of the Assignment Notice: (i) grant such consent, (ii) refuse such consent, in its reasonable discretion, or (iii) with respect to any assignment or any sublease that would result in more than 50% of the Premises being subleased for substantially the remainder of the Term, terminate this Lease with respect to the space described in the Assignment Notice as of the Assignment Date (an "**Assignment Termination**"). If Landlord delivers notice of its election to exercise an Assignment Termination, Tenant shall have the right to withdraw such Assignment Notice by written notice to Landlord of such election within 5 business days after Landlord's notice electing to exercise the Assignment Termination. If Tenant withdraws such Assignment Notice, this Lease shall continue in full force and effect. If Tenant does not withdraw such Assignment Notice, this Lease, and the term and estate herein granted, shall terminate as of the Assignment Date with respect to the space described in such Assignment Notice. No failure of Landlord to exercise any such option to terminate this Lease, or to deliver a timely notice in response to the Assignment Notice, shall be deemed to be Landlord's consent to the proposed assignment, sublease or other transfer. It shall be reasonable for Landlord to withhold its consent, among other reasons, in any of the following instances: (1) the proposed assignee or subtenant is a governmental agency; (2) in Landlord's reasonable judgment, the use of the Premises by the proposed

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assignee or subtenant would entail any alterations that would lessen the value of the leasehold improvements in the Premises, or would require increased services by Landlord; (3) in Landlord's reasonable judgment, the proposed assignee or subtenant is engaged in areas of scientific research or other business concerns that are controversial; (4) in Landlord's reasonable judgment, the proposed assignee or subtenant lacks the creditworthiness to support the financial obligations it will incur under the proposed assignment or sublease; (5) in Landlord's reasonable judgment, the character, reputation, or business of the proposed assignee or subtenant is inconsistent with the desired tenant-mix or the quality of other tenancies in the Project or is inconsistent with the type and quality of the nature of the Building; (6) Landlord has experienced previous defaults by or is in litigation with the proposed assignee or subtenant; (7) the use of the Premises by the proposed assignee or subtenant will violate any applicable Legal Requirement; or (8) the assignment or sublease is prohibited by Landlord's lender. In any event, Landlord shall further have the right to review and approve or disapprove the proposed form of sublease prior to the effective date of any such subletting. Other than in connection with any Permitted Assignment or Shared Space Arrangement, Tenant shall pay to Landlord a fee equal to Three Thousand Dollars (\$3,000) in connection with its consideration of any Assignment Notice and/or its preparation or review of any consent documents.

(c) **Affiliate Transactions.** Notwithstanding the foregoing, Landlord's consent to an assignment of this Lease or a subletting of any portion of the Premises to any entity funded wholly or in part by Flagship Pioneering, Inc., a Delaware corporation, or any of its fund affiliates (each such entity, a "**Flagship Pioneering Entity**") or to any entity controlling, controlled by or under common control with Tenant (a "**Control Permitted Assignment**") shall not be required, provided that Landlord shall have the right to reasonably approve the form of any such sublease or assignment. In addition, Tenant shall have the right to assign this Lease, upon 10 days' prior written notice to Landlord ((x) unless Tenant is prohibited from providing such notice by applicable Legal Requirements in which case Tenant shall notify Landlord promptly thereafter, and (y) if the transaction is subject to confidentiality requirements, Tenant's advance notification shall be subject to Landlord's execution of a non-disclosure agreement reasonably acceptable to Landlord and Tenant) but without obtaining Landlord's prior written consent, to a corporation or other entity which is a successor-in-interest to Tenant, by way of merger, consolidation or corporate reorganization, or by the purchase of all or substantially all of the assets or the ownership interests of Tenant provided that (i) such merger or consolidation, or such acquisition or assumption, as the case may be, is for a good business purpose and not principally for the purpose of transferring the Lease, and (ii) the net worth (as determined in accordance with generally accepted accounting principles ("**GAAP**")) of the assignee is not less than the greater of the net worth (as determined in accordance with GAAP) of Tenant as of (A) the Commencement Date, or (B) as of the date of Tenant's most current quarterly or annual financial statements, and (iii) such assignee shall agree in writing to assume all of the terms, covenants and conditions of this Lease (a "**Corporate Permitted Assignment**"). Control Permitted Assignments and Corporate Permitted Assignments are hereinafter referred to as "**Permitted Assignments.**"

Notwithstanding anything to the contrary contained in this Lease, Tenant may from time to time enter into license agreements (each, a "**Shared Space Arrangement**") with affiliates of any Flagship Pioneering Entity (each, a "**Space Occupant**") to use portions of the Premises as "**Shared Space Area**" for a period not to exceed 12 months in the aggregate, and such Shared Space Arrangements shall not require Landlord's consent under Section 22 of this Lease but Tenant shall be required to provide Landlord with a copy of each such Shared Space Arrangement and, prior to the effective date of each such Shared Space Arrangement and prior to any use of the Premises by such Space Occupant, Tenant

and each licensee shall be required to execute Landlord's consent in the form attached hereto as **Exhibit G**. The rights set forth in this paragraph are personal to Omega Therapeutics, Inc., and any assignee of Omega Therapeutics, Inc. pursuant to a Permitted Assignment and, except with respect to such assignee pursuant to a Permitted Assignment, shall not inure to the benefit of any successor, assignee or subtenant of Omega Therapeutics, Inc. Tenant shall be fully responsible for the conduct of all Space Occupants and the agents, servants, employees, invitees and contractors of each Space Occupant within the Shared Space Area and the Project, and Tenant's indemnification obligations set forth in the Lease shall apply with respect to the conduct of such parties within the Shared Space Area and Project.

(d) **Additional Conditions.** As a condition to any such assignment or subletting, whether or

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not Landlord's consent is required, Landlord may require:

(i) that any assignee or subtenant agree, in writing at the time of such assignment or subletting, that if Landlord gives such party notice that Tenant is in default under this Lease, such party shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments will be received by Landlord without any liability except to credit such payment against those due under this Lease, and any such third party shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, in no event shall Landlord or its successors or assigns be obligated to accept such attornment; and

(ii) A list of Hazardous Materials, certified by the proposed assignee or sublessee to be true and correct, which the proposed assignee or sublessee intends to use, store, handle, treat, generate in or release or dispose of from the Premises, together with copies of all documents relating to such use, storage, handling, treatment, generation, release or disposal of Hazardous Materials by the proposed assignee or subtenant in the Premises or on the Project, prior to the proposed assignment or subletting, including, without limitation: permits; approvals; reports and correspondence; storage and management plans; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); and all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks. Neither Tenant nor any such proposed assignee or subtenant is required, however, to provide Landlord with any portion(s) of the such documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities.

(e) **No Release of Tenant, Sharing of Excess Rents.** Notwithstanding any assignment or subletting, except as otherwise provided in the immediately following sentence, Tenant and any guarantor or surety of Tenant's obligations under this Lease shall at all times remain fully and primarily responsible and liable for the payment of Rent and for compliance with all of Tenant's other obligations under this Lease. If any then-current Tenant entity ("**Transferring Tenant Entity**") assigns its interests under this Lease to a Flagship Pioneering Entity and such Flagship Pioneering Entity assumes liability under this Lease from the Commencement Date as though it was an original Tenant under this Lease, then the Transferring Tenant Entity shall, as of the date of the transfer of such interests to the Flagship Pioneering Entity, be released from liability under this Lease first arising after the date of such transfer. If the Rent due and payable by a sublessee or assignee (or a combination of the rental payable under such sublease or assignment plus any bonus or other consideration therefor or incident thereto in any form) exceeds the sum of the rental payable under this Lease with respect to the applicable portion of the Premises (excluding however, any Rent payable under this Section) after first deducting actual and reasonable and customary brokerage fees, legal costs, advertising expenses, free rent or other reasonable concessions and any design or construction fees and tenant improvement costs directly related to and required pursuant to the terms of any such sublease) ("**Excess Rent**"), then Tenant shall be bound and obligated to pay Landlord as Additional Rent hereunder 50% of such Excess Rent within 30 days following receipt thereof by Tenant. If Tenant shall sublet the Premises or any part thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and Landlord as assignee for Tenant, or a receiver for Tenant appointed on Landlord's application, may collect such rent and apply it toward Tenant's obligations under this Lease; except that, until the occurrence of a Default, Tenant shall have the right to collect such rent.

(f) **No Waiver.** The consent by Landlord to an assignment or subletting shall not relieve Tenant or any assignees of this Lease or any sublessees of the Premises from obtaining the consent of Landlord to any further assignment or subletting nor shall it release Tenant or any assignee or sublessee of Tenant from full and primary liability under this Lease. The acceptance of Rent hereunder, or the acceptance of performance of any other term, covenant, or condition thereof, from any other person or entity shall not be deemed to be a waiver of any of the provisions of this Lease or a consent to any subletting, assignment or other transfer of the Premises.

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(g) **Notice Requirement.** Notwithstanding anything to the contrary contained in the Lease, in no event may Tenant permit any party (including, without limitation, any business entity or any employees or invitees of such business entity) to occupy or use all or any portion of the Premises during the Term for the purpose of conducting any business therein (whether pursuant to an assignment, sublease, license or otherwise) without Tenant having delivered to Landlord prior written notice of the prospective occupancy or use of the Premises by such party. In addition, upon written request from Landlord, Tenant shall provide such additional information as may be requested by Landlord including, without limitation, the names of all parties and individuals who are then using or occupying all or any portion of the Premises, so that Landlord is aware at all times of who is using or occupying all or any portion of the Premises.

(h) **Prior Conduct of Proposed Transferee.** Notwithstanding any other provision of this Section 22, if (i) the proposed assignee or sublessee of Tenant has been required by any prior landlord, lender or Governmental Authority to take remedial action in connection with Hazardous Materials contaminating a property, where the contamination resulted from such party's action or use of the property in question, (ii) the proposed assignee or sublessee is subject to an enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority), or (iii) because of the existence of a pre-existing environmental condition in the vicinity of or underlying the Project, the risk that Landlord would be targeted as a responsible party in connection with the remediation of such pre-existing environmental condition would be materially increased or exacerbated by the proposed use of Hazardous Materials by such proposed assignee or sublessee, Landlord shall have the absolute right to refuse to consent to any assignment or subletting to any such party.

**23. Estoppel Certificate.** Tenant shall, within 10 business days of written notice from Landlord, execute, acknowledge and deliver a statement in writing in any form reasonably requested by a proposed lender or purchaser, (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which the rental and other charges are paid in advance, if any, (ii) acknowledging, to the best of Tenant's knowledge, that there are not any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (iii) setting forth such further information with respect to the status of this Lease or the Premises as may be reasonably requested thereon. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Premises are a part. If Tenant does not respond within 5 days of a second written request for such statement, Tenant's failure to deliver such statement within such time shall, at the option of Landlord, be conclusive upon Tenant that the Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.

**24. Quiet Enjoyment.** So long as Tenant is not in Default under this Lease, Tenant shall, subject to the terms of this Lease, at all times during the Term, have peaceful and quiet enjoyment of the Premises against any person claiming by, through or under Landlord.

**25. Prorations.** All prorations required or permitted to be made hereunder shall be made on the basis of a 360 day year and 30 day months.

**26. Rules and Regulations.** Tenant shall, at all times during the Term and any extension thereof, comply with all reasonable rules and regulations (written notice of which has been delivered to Tenant) at any time or from time to time established by Landlord covering use of the Premises and the Project. Such rules and regulations may include, without limitation, rules and regulations relating to the use of the Project Amenities and/or rules and regulations which are intended to encourage social distancing, promote and protect health and physical well-being within the Building and the Project and/or intended to limit the spread of Infectious Conditions. The current rules and regulations are attached hereto as **Exhibit E**. If there is any conflict between said rules and regulations and other provisions of this Lease, the terms and provisions of this Lease shall control. Landlord shall not have any liability or obligation for the breach of any rules or regulations by other tenants in the Project and shall not enforce such rules and regulations

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in a discriminatory manner.

**27. Subordination.** This Lease and Tenant's interest and rights hereunder are hereby made and shall be subject and subordinate at all times to the lien of any Mortgage now existing or hereafter created on or against the Project, Property, Building or Premises, and all amendments, restatements, renewals, modifications, consolidations, refinancing, assignments and extensions thereof, without the necessity of any further instrument or act on the part of Tenant; provided, however that so long as there is no Default hereunder, Tenant's right to possession of the Premises shall not be disturbed by the Holder of any such Mortgage. Tenant agrees, at the election of the Holder of any such Mortgage, to attorn to any such Holder. Tenant's agreement to subordinate this Lease to any future deed of trust or mortgage pursuant to this Section 27 is conditioned upon Landlord delivering to Tenant from the Holder of any such mortgage or deed of trust a commercially reasonable non-disturbance and attornment agreement and Tenant shall not unreasonably withhold, condition or delay its approval of the same. Tenant agrees upon written demand to execute, acknowledge and deliver such instruments, confirming such subordination, and such instruments of attornment as shall be requested by any such Holder, provided any such instruments contain appropriate non-disturbance provisions assuring Tenant's quiet enjoyment of the Premises as set forth in Section 24 hereof. Notwithstanding the foregoing, any such Holder may at any time subordinate its Mortgage to this Lease, without Tenant's consent, by notice in writing to Tenant, and thereupon this Lease shall be deemed prior to such Mortgage without regard to their respective dates of execution, delivery or recording and in that event such Holder shall have the same rights with respect to this Lease as though this Lease had been executed prior to the execution, delivery and recording of such Mortgage and had been assigned to such Holder. The term "**Mortgage**" whenever used in this Lease shall be deemed to include deeds of trust, security assignments, ground leases or other superior leases and any other encumbrances, and any reference to the "**Holder**" of a Mortgage shall be deemed to include the beneficiary under a deed of trust.

**28. Surrender.** Upon the expiration of the Term or earlier termination of Tenant's right of possession, Tenant shall surrender the Premises to Landlord in the same condition as received, subject to any Alterations or Installations permitted by Landlord to remain in the Premises, free of Hazardous Materials brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person other than a Landlord Party (collectively, "**Tenant HazMat Operations**") and released of all Hazardous Materials Clearances, broom clean, ordinary wear and tear and casualty loss and condemnation covered by Sections 18 and 19 excepted. At least 3 months prior to the surrender of the Premises or such earlier date as Tenant may elect to cease operations at the Premises, Tenant shall deliver to Landlord a narrative description of the actions proposed (or required by any Governmental Authority) to be taken by Tenant in order to surrender the Premises (including any Installations permitted by Landlord to remain in the Premises) at the expiration or earlier termination of the Term, free from any residual impact from the Tenant HazMat Operations and otherwise released for unrestricted use and occupancy (the "**Decommissioning and HazMat Closure Plan**"). Such Decommissioning and HazMat Closure Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of any Tenant Party with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Landlord's environmental consultant. Landlord shall use reasonable efforts to cause Landlord's environmental consultant to provide Tenant with comments to or approval of, as the case may be, the Decommissioning and HazMat Closure Plan within a reasonable time after Tenant delivers the Decommissioning and HazMat Closure Plan to Landlord. In connection with the review and approval of the Decommissioning and Decommissioning and HazMat Closure Plan, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning Tenant HazMat Operations as Landlord shall request. On or before such surrender, Tenant shall deliver to Landlord evidence that the approved Decommissioning and HazMat Closure Plan shall have been satisfactorily completed and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the effective date of such surrender or early termination of the Lease, free from any residual impact from Tenant HazMat Operations. Tenant shall reimburse Landlord, as Additional Rent, for the actual out-of-pocket expense incurred by Landlord for Landlord's environmental consultant to review and approve the Decommissioning

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and HazMat Closure Plan and to visit the Premises and verify satisfactory completion of the same, which cost shall not exceed \$5,000. Landlord shall have the unrestricted right to deliver such Decommissioning and HazMat Closure Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties, provided that Landlord instructs such third parties to treat the same as confidential.

If Tenant shall fail to prepare or submit a Decommissioning and HazMat Closure Plan approved by Landlord, or if Tenant shall fail to complete the approved Decommissioning and HazMat Closure Plan, or if such Decommissioning and HazMat Closure Plan, whether or not approved by Landlord, shall fail to adequately address any residual effect of Tenant HazMat Operations in, on or about the Premises, Landlord shall have the right to take such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Project are surrendered free from any residual impact from Tenant HazMat Operations, the actual cost of which actions shall be reimbursed by Tenant as Additional Rent, without regard to the limitation set forth in the first paragraph of this Section 28.

Upon the expiration or earlier termination of the Term, Tenant shall immediately return to Landlord all keys and/or access cards to parking, the Building, restrooms or all or any portion of the Premises, Building or Project furnished to or otherwise procured by Tenant. If any such access card or key is lost, Tenant shall pay to Landlord, at Landlord's election, either the cost of replacing such lost access card or key or the cost of reprogramming the access security system in which such access card was used or changing the lock or locks opened by such lost key. Any Tenant's Property, Alterations and other property of Tenant not so removed by Tenant as permitted or required herein shall be deemed abandoned and may be stored, removed, and disposed of by Landlord at Tenant's expense, and Tenant waives all claims against Landlord for any damages resulting from Landlord's retention and/or disposition of such property. All obligations of Tenant hereunder not fully performed as of the termination of the Term, including the obligations of Tenant under Section 30 hereof, shall survive the expiration or earlier termination of the Term, including, without limitation, indemnity obligations, payment obligations with respect to Rent and obligations concerning the condition and repair of the Premises.

**29. Waiver of Jury Trial.** TO THE EXTENT PERMITTED BY LAW, TENANT AND LANDLORD WAIVE ANY RIGHT TO TRIAL BY JURY OR TO HAVE A JURY PARTICIPATE IN RESOLVING ANY DISPUTE, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE, BETWEEN LANDLORD AND TENANT ARISING OUT OF THIS LEASE OR ANY OTHER INSTRUMENT, DOCUMENT, OR AGREEMENT EXECUTED OR DELIVERED IN CONNECTION HERewith OR THE TRANSACTIONS RELATED HERETO.

### **30. Environmental Requirements.**

(a) **Prohibition/Compliance/Indemnity.** Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises, Building, Property or Project in violation of applicable Environmental Requirements (as hereinafter defined) by Tenant or any Tenant Party. If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials in the Premises during the Term or any holding over results in contamination of the Premises, Building, Property or Project or any adjacent property or if contamination of the Premises, Building, Property or Project or any adjacent property by Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises by anyone other than Landlord and Landlord's employees, agents and contractors otherwise occurs during the Term or any holding over, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, agents and contractors harmless from any and all actions (including, without limitation, remedial or enforcement actions of any kind, administrative or judicial proceedings, and orders or judgments arising out of or resulting therefrom), costs, claims, damages (including, without limitation, punitive damages and damages based upon diminution in value of the Premises or the Project, or the loss of, or restriction on, use of the Premises or any portion of the Project), expenses (including, without limitation, attorneys', consultants' and experts' fees, court costs and amounts paid in settlement of any claims or actions), fines, forfeitures or other civil, administrative or criminal penalties, injunctive or other relief (whether or not based upon personal injury, property damage, or contamination of, or adverse effects upon, the environment, water tables or natural resources), liabilities

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or losses (collectively, "**Environmental Claims**") which arise during or after the Term as a result of such breach of Tenant's obligations stated in the preceding sentence or as a result of such contamination. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, treatment, remedial, removal, or restoration work required by any federal, state or local Governmental Authority because of Hazardous Materials present in the air, soil or ground water above, on, or under the Premises. Without limiting the foregoing, if the presence of any Hazardous Materials on the Premises, Building, Property, Project or any adjacent property caused or permitted by Tenant or any Tenant Party results in any contamination of the Premises, Building, Property, Project or any adjacent property, Tenant shall promptly take all actions at its sole expense and in accordance with applicable Environmental Requirements as are necessary to return the Premises, Building, Property, Project or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord's approval of such action shall first be obtained, which approval shall not unreasonably be withheld so long as such actions would not potentially have any material adverse long-term or short-term effect on the Premises, Building, Property or the Project. Notwithstanding anything to the contrary contained in Section 28 or this Section 30, Tenant shall not be responsible for, and the indemnification and hold harmless obligations set forth in this paragraph shall not apply to (i) contamination in the Premises which Tenant can prove to Landlord's reasonable satisfaction existed in the Premises prior to the Commencement Date, (ii) the presence of any Hazardous Materials in the Premises which Tenant can prove to Landlord's reasonable satisfaction migrated from outside the Premises into the Premises, or (iii) contamination caused by Landlord or any Landlord's employees, agents and contractors, unless in any case, the presence of such Hazardous Materials (x) is the result of a breach by Tenant of any of its obligations under this Lease, or (y) was caused, contributed to or exacerbated by Tenant or any Tenant Party.

(b) **Business.** Landlord acknowledges that it is not the intent of this Section 30 to prohibit Tenant from using the Premises for the Permitted Use. Tenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all then applicable Environmental Requirements. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Commencement Date a list identifying each type of Hazardous Materials to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises ("**Hazardous Materials List**"). Upon Landlord's request, or any time that Tenant is required to deliver a Hazardous Materials List to any Governmental Authority (e.g., the fire department) in connection with Tenant's use or occupancy of the Premises, Tenant shall deliver to Landlord a copy of such Hazardous Materials List. Notwithstanding the foregoing, the Hazardous Materials List shall not be required to include Hazardous Materials contained in products customarily used by tenants in de minimis quantities for ordinary cleaning and office purposes. Tenant shall deliver to Landlord true and correct copies of the following documents (the "**Haz Mat Documents**") relating to the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials prior to the Commencement Date, or if unavailable at that time, concurrent with the receipt from or submission to a Governmental Authority: permits; approvals; reports and correspondence; storage and management plans, notice of violations of any Legal Requirements; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks; and a Decommissioning and HazMat Closure Plan (to the extent surrender in accordance with Section 28 cannot be accomplished in 3 months). Tenant is not required, however, to provide Landlord with any portion(s) of the Haz Mat Documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities. It is not the intent of this Section to provide Landlord with information which could be detrimental to Tenant's business should such information become possessed by Tenant's competitors.

(c) **Tenant Representation and Warranty.** Tenant hereby represents and warrants to Landlord that (i) neither Tenant nor any of its legal predecessors has been required by any prior landlord,

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lender or Governmental Authority at any time to take remedial action in connection with Hazardous Materials contaminating a property which contamination was permitted by Tenant or such predecessor or resulted from Tenant's or such predecessor's action or use of the property in question, and (ii) Tenant is not subject to any enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority). If Landlord determines that this representation and warranty was not true as of the date of this lease, Landlord shall have the right to terminate this Lease in Landlord's sole and absolute discretion.

(d) **Testing.** Landlord shall have the right to conduct annual tests of the Premises to determine whether any contamination of the Premises, Building, Property or Project has occurred as a result of Tenant's use. Tenant shall be required to pay the cost of such annual test of the Premises if there is a violation of this Section 30 or if contamination for which Tenant is responsible under this Section 30 is identified; provided, however, that if Tenant conducts its own tests of the Premises using third party contractors and test procedures acceptable to Landlord which tests are certified to Landlord, Landlord shall accept such tests in lieu of the annual tests to be paid for by Tenant. In addition, at any time, and from time to time, prior to the expiration or earlier termination of the Term, Landlord shall have the right to conduct appropriate tests of the Premises, Building, Property and Project to determine if contamination has occurred as a result of Tenant's use of the Premises. In connection with such testing, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such non-proprietary information concerning the use of Hazardous Materials in or about the Premises by Tenant or any Tenant Party. If contamination has occurred for which Tenant is liable under this Section 30, Tenant shall pay all costs to conduct such tests. If no such contamination is found, Landlord shall pay the costs of such tests (which shall not constitute an Operating Expense). Landlord shall provide Tenant with a copy of all third party, non-confidential reports and tests of the Premises made by or on behalf of Landlord during the Term without representation or warranty and subject to a confidentiality agreement. Tenant shall, at its sole cost and expense, promptly and satisfactorily remediate any environmental conditions identified by such testing for which Tenant is responsible for under Section 30 in accordance with all Environmental Requirements. Landlord's receipt of or satisfaction with any environmental assessment in no way waives any rights which Landlord may have against Tenant.

(e) **Control Areas.** Tenant shall be allowed to utilize up to its pro rata share of the Hazardous Materials inventory within any control area or zone (located within the Premises), as designated by the applicable building code, for chemical use or storage. As used in the preceding sentence, Tenant's pro rata share of any control areas or zones located within the Premises shall be determined based on the rentable square footage that Tenant leases within the applicable control area or zone. For purposes of example only, if a control area or zone contains 10,000 rentable square feet and 2,000 rentable square feet of a tenant's premises are located within such control area or zone (while such premises as a whole contains 5,000 rentable square feet), the applicable tenant's pro rata share of such control area would be 20%.

(f) **Storage Tanks.** If storage tanks storing Hazardous Materials located on the Premises or the Project are used by Tenant or are hereafter placed on the Premises or the Project by Tenant, Tenant shall install, use, monitor, operate, maintain, upgrade and manage such storage tanks, maintain appropriate records, obtain and maintain appropriate insurance, implement reporting procedures, properly close any storage tanks, and take or cause to be taken all other actions necessary or required under applicable state and federal Legal Requirements, as such now exists or may hereafter be adopted or amended in connection with the installation, use, maintenance, management, operation, upgrading and closure of such storage tanks. Notwithstanding anything to the contrary contained herein, Tenant shall have no right to use or install any underground storage tanks at the Project.

(g) **Tenant's Obligations.** Tenant's obligations under this Section 30 shall survive the expiration or earlier termination of this Lease. During any period of time after the expiration or earlier termination of this Lease required by Tenant or Landlord to complete the removal from the Premises of any Hazardous Materials for which Tenant is responsible under this Lease (including, without limitation, the release and termination of any licenses or permits restricting the use of the Premises and the completion of the approved Decommissioning and HazMat Closure Plan), Tenant shall continue to pay the full Rent in accordance with this Lease for any portion of the Premises not relet by Landlord in Landlord's sole discretion, which Rent shall be prorated daily.

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(h) **Definitions.** As used herein, the term “**Environmental Requirements**” means all applicable present and future statutes, regulations, ordinances, rules, codes, judgments, orders or other similar enactments of any Governmental Authority regulating or relating to health, safety, or environmental conditions on, under, or about the Premises or the Project, or the environment, including without limitation, the following: the Comprehensive Environmental Response, Compensation and Liability Act; the Resource Conservation and Recovery Act; and all state and local counterparts thereto, and any regulations or policies promulgated or issued thereunder. As used herein, the term “**Hazardous Materials**” means and includes any substance, material, waste, pollutant, or contaminant listed or defined as hazardous or toxic, or regulated by reason of its impact or potential impact on humans, animals and/or the environment under any Environmental Requirements, asbestos and petroleum, including crude oil or any fraction thereof, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). As defined in Environmental Requirements, Tenant is and shall be deemed to be the “**operator**” of Tenant’s “**facility**” and the “**owner**” of all Hazardous Materials brought on the Premises by Tenant or any Tenant Party, and the wastes, by-products, or residues generated, resulting, or produced therefrom.

**31. Tenant’s Remedies/Limitation of Liability.** Landlord shall not be in default hereunder unless Landlord fails to perform any of its obligations hereunder within 30 days after written notice from Tenant specifying such failure (unless such performance will, due to the nature of the obligation, require a period of time in excess of 30 days, then after such period of time as is reasonably necessary). Upon any default by Landlord, Tenant shall give written notice, via reputable overnight guaranty courier, to any Holder of a Mortgage covering the Premises and to any landlord of any lease of property in or on which the Premises are located and Tenant shall offer such Holder and/or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Project, or portion thereof of which the Premises are a part, by power of sale or a judicial action if such should prove necessary to effect a cure; provided Landlord shall have furnished to Tenant in writing the names and addresses of all such persons who are to receive such notices. All obligations of Landlord hereunder shall be construed as covenants, not conditions; and, except as may be otherwise expressly provided in this Lease, Tenant may not terminate this Lease for breach of Landlord’s obligations hereunder.

All obligations of Landlord under this Lease will be binding upon Landlord only during the period of its ownership of the Premises and not thereafter. The term “**Landlord**” in this Lease shall mean only the owner for the time being of the Premises. Upon the transfer by such owner of its interest in the Premises, such owner shall thereupon be released and discharged from all obligations of Landlord thereafter accruing, but such obligations shall be binding during the Term upon each new owner for the duration of such owner’s ownership.

**32. Inspection and Access.** Landlord and its agents, representatives, and contractors may enter the Premises at any reasonable time to inspect the Premises and to make such repairs as may be required or permitted pursuant to this Lease and for any other business purpose. Landlord and Landlord’s representatives may enter the Premises during business hours on not less than 48 hours advance written notice (except in the case of emergencies in which case no such notice shall be required and such entry may be at any time) for the purpose of effecting any such repairs, inspecting the Premises, showing the Premises to prospective purchasers and, during the last 15 months of the Term, to prospective tenants or for any other business purpose. Landlord may erect a suitable sign on the Premises stating that the Project is available for sale, or in the last 15 months of the Term, that the Premises are available to let. Landlord shall use reasonable efforts to minimize interference with Tenant’s business operations at the Premises in connection with its entry into the Premises under this Section 32. Landlord may grant and amend easements, make public dedications, designate Common Areas and create restrictions on or about the Project (excluding the Premises), provided that no such easement, dedication, designation or restriction materially, adversely affects Tenant’s use or occupancy of the Premises for the Permitted Use. At Landlord’s request, Tenant shall execute such instruments as may be necessary for such easements, dedications or restrictions. Tenant shall at all times, except in the case of emergencies, have the right to escort Landlord or its agents, representatives, contractors or guests while the same are in the Premises, provided such escort does not materially and adversely affect Landlord’s access rights hereunder. Landlord

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shall use reasonable efforts to comply with Tenant's reasonable security, confidentiality and safety requirements with respect to entering restricted portions of the Premises; provided, however, that Tenant has notified Landlord of such security, confidentiality and safety requirements reasonably prior to Landlord's entry into the Premises and provided further that in no event shall Tenant bar or prohibit access by Landlord and its employees, agents and contractors for the performance of the obligations of Landlord or the exercise of the rights of Landlord under this Lease.

Notwithstanding the foregoing, Tenant shall have the right to designate (on plans provided by Tenant to Landlord, which may be reasonably updated by Tenant from time to time upon notice to Landlord) certain areas of the Premises as limited access areas required to protect the health of persons or security of confidential and proprietary information ("**Limited Access Areas**"), which Limited Access Areas shall not be entered into by Landlord or Landlord's representatives without a Tenant representative, except in the case of an emergency. Notwithstanding anything to the contrary contained in this Lease, Landlord shall not provide janitorial services any area designated by Tenant as a Limited Access Area and shall only enter such Limited Access Areas to perform maintenance and repairs (i) for which Landlord is responsible under this Lease, or (ii) in response to specific requests by Tenant, which requests remain subject to Landlord's approval.

**33. Security.** Tenant acknowledges and agrees that security devices and services, if any, while intended to deter crime may not in given instances prevent theft or other criminal acts and that Landlord is not providing any security services with respect to the Premises. Tenant agrees that Landlord shall not be liable to Tenant for, and Tenant waives any claim against Landlord with respect to, any loss by theft or any other damage suffered or incurred by Tenant in connection with any unauthorized entry into the Premises or any other breach of security with respect to the Premises. Tenant shall be solely responsible for the personal safety of Tenant's officers, employees, agents, contractors, guests and invitees while any such person is in, on or about the Premises, Building, Property and/or Project. Tenant shall at Tenant's cost obtain insurance coverage to the extent Tenant desires protection against such criminal acts.

**34. Force Majeure.** Except for the payment of Rent and any other amounts payable under this Lease, neither Landlord nor Tenant shall be held responsible or liable for delays in the performance of its obligations hereunder when caused by, related to, or arising out of acts of God, strikes, lockouts, or other labor disputes, embargoes, quarantines, abnormal weather, national, regional, or local disasters, calamities, or catastrophes, inability to obtain labor or materials (or reasonable substitutes therefor) at reasonable costs or failure of, or inability to obtain, utilities necessary for performance, governmental restrictions, orders, limitations, regulations, or controls, national emergencies, local, regional or national epidemic or pandemic, delay in issuance or revocation of permits, enemy or hostile governmental action, terrorism, insurrection, riots, civil disturbance or commotion, fire or other casualty, and other causes or events beyond their reasonable control ("**Force Majeure**"). Landlord and Tenant, as the case may be, shall take reasonable measures to mitigate and minimize the impact of any such Force Majeure.

**35. Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with this transaction and that no Broker brought about this transaction, other than Newmark. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than Newmark, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

**36. Limitation on Landlord's Liability.** NOTWITHSTANDING ANYTHING SET FORTH HEREIN OR IN ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT TO THE CONTRARY: (A) LANDLORD SHALL NOT BE LIABLE TO TENANT OR ANY OTHER PERSON FOR (AND TENANT AND EACH SUCH OTHER PERSON ASSUME ALL RISK OF) LOSS, DAMAGE OR INJURY, WHETHER ACTUAL OR CONSEQUENTIAL TO: TENANT'S PERSONAL PROPERTY OF EVERY KIND AND DESCRIPTION, INCLUDING, WITHOUT LIMITATION TRADE FIXTURES, EQUIPMENT, INVENTORY, SCIENTIFIC RESEARCH, SCIENTIFIC EXPERIMENTS, LABORATORY ANIMALS, PRODUCT, SPECIMENS, SAMPLES, AND/OR SCIENTIFIC, BUSINESS, ACCOUNTING AND OTHER RECORDS

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OF EVERY KIND AND DESCRIPTION KEPT AT THE PREMISES AND ANY AND ALL INCOME DERIVED OR DERIVABLE THEREFROM; (B) THERE SHALL BE NO PERSONAL RECOURSE TO LANDLORD FOR ANY ACT OR OCCURRENCE IN, ON OR ABOUT THE PREMISES OR ARISING IN ANY WAY UNDER THIS LEASE OR ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT WITH RESPECT TO THE SUBJECT MATTER HEREOF AND ANY LIABILITY OF LANDLORD HEREUNDER SHALL BE STRICTLY LIMITED SOLELY TO LANDLORD'S INTEREST IN THE PROJECT OR ANY PROCEEDS FROM SALE OR CONDEMNATION THEREOF AND ANY INSURANCE PROCEEDS PAYABLE IN RESPECT OF LANDLORD'S INTEREST IN THE PROJECT OR IN CONNECTION WITH ANY SUCH LOSS; AND (C) IN NO EVENT SHALL ANY PERSONAL LIABILITY BE ASSERTED AGAINST LANDLORD IN CONNECTION WITH THIS LEASE NOR SHALL ANY RECOURSE BE HAD TO ANY OTHER PROPERTY OR ASSETS OF LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS. UNDER NO CIRCUMSTANCES SHALL LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS BE LIABLE FOR INJURY TO TENANT'S BUSINESS OR FOR ANY LOSS OF INCOME OR PROFIT THEREFROM.

NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS LEASE, IN NO EVENT SHALL PERSONAL LIABILITY FOR TENANT'S OBLIGATIONS UNDER THIS LEASE BE ASSERTED AGAINST ANY OF TENANT'S OFFICERS, DIRECTORS, EMPLOYEES OR AGENTS.

Tenant acknowledges and agrees that measures and/or services implemented at the Project, if any, intended to encourage social distancing, promote and protect health and physical well-being and/or intended to limit the spread of Infectious Conditions, may not prevent the spread of such Infectious Conditions. Neither Landlord nor any Landlord Indemnified Parties shall have any liability and Tenant waives any claims against Landlord and the Landlord Indemnified Parties with respect to any loss, damage or injury in connection with (x) the implementation, or failure of Landlord or any Landlord Indemnified Parties to implement, any measures and/or services at the Project intended to encourage social distancing, promote and protect health and physical well-being and/or intended to limit the spread of Infectious Conditions, or (y) the failure of any measures and/or services implemented at the Project, if any, to limit the spread of any Infectious Conditions.

**37. Severability.** If any clause or provision of this Lease is illegal, invalid or unenforceable under present or future laws, then and in that event, it is the intention of the parties hereto that the remainder of this Lease shall not be affected thereby. It is also the intention of the parties to this Lease that in lieu of each clause or provision of this Lease that is illegal, invalid or unenforceable, there be added, as a part of this Lease, a clause or provision as similar in effect to such illegal, invalid or unenforceable clause or provision as shall be legal, valid and enforceable.

**38. Signs; Exterior Appearance.** Tenant shall not, without the prior written consent of Landlord, which may be granted or withheld in Landlord's reasonable discretion: (i) attach any awnings, exterior lights, decorations, balloons, flags, pennants, banners, painting or other projection to any outside wall of the Building, (ii) use any curtains, blinds, shades or screens other than Landlord's standard window coverings, (iii) coat or otherwise sunscreen the interior or exterior of any windows, (iv) place any bottles, parcels, or other articles on the window sills, (v) place any equipment, furniture or other items of personal property on any exterior balcony, or (vi) paint, affix or exhibit on any part of the Premises, Building, Property or Project any signs, notices, window or door lettering, placards, decorations, or advertising media of any type which can be viewed from the exterior of the Premises. Notwithstanding the forgoing, Tenant shall be permitted to have furniture on the balcony on the fifth floor, subject to Landlord's approval, which shall not to be unreasonably withheld, conditioned or delayed. Suite entry signage and Tenant's name and location on the Building lobby directory shall be inscribed, painted or affixed for Tenant by Landlord at the sole cost and expense of Tenant, and shall be of a size, color and type acceptable to Landlord. Nothing may be placed on the exterior of corridor walls or corridor doors other than Landlord's standard lettering. The Building lobby directory shall be provided exclusively for the display of the name and location of tenants.

**39. Right to Extend Term.** Tenant shall have the right to extend the Term of this Lease upon the following terms and conditions:

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(a) **Extension Rights.** Tenant shall have 3 consecutive rights (each, an “**Extension Right**”) to extend the term of this Lease for 60 months each (each, an “**Extension Term**”) on the same terms and conditions as this Lease (other than with respect to Base Rent and the Work Letter) by giving Landlord written notice of its election to exercise each Extension Right at least 12 months prior, and no earlier than 15 months prior, to the expiration of the Base Term of this Lease or the expiration of any prior Extension Term.

Upon the commencement of the Extension Term, Base Rent shall be payable at the Market Rate (as defined below). Base Rent shall thereafter be adjusted on each annual anniversary of the commencement of the Extension Term by a percentage as determined by Landlord and agreed to by Tenant at the time the Market Rate is determined. As used herein, “**Market Rate**” shall mean the rate that comparable landlords of comparable buildings have accepted in current transactions from non-equity (i.e., not being offered equity in the buildings) and nonaffiliated tenants of similar financial strength for space of comparable size, quality (including all Tenant Improvements, Alterations and other improvements) and floor height in Class A laboratory/office buildings in the East Cambridge and Kendall Square market area of Cambridge, Massachusetts for a comparable term, with the determination of the Market Rate to take into account all relevant factors, including tenant inducements, views, parking costs, available amenities (including the Project Amenities), leasing commissions, allowances or concessions, if any. Notwithstanding the foregoing, the Market Rate shall in no event be less than the Base Rent payable as of the date immediately preceding the commencement of such Extension Term. In addition, Landlord may impose a market rent for the parking rights provided hereunder.

If, on or before the date which is 270 days prior to the expiration of the Base Term of this Lease or the expiration of the prior Extension Term, as applicable, Tenant has not agreed with Landlord’s determination of the Market Rate and the rent escalations during the applicable Extension Term after negotiating in good faith, Tenant shall be deemed to have elected arbitration as described in Section 39(b). Tenant acknowledges and agrees that, if Tenant has elected to exercise an Extension Right by delivering notice to Landlord as required in this Section 39(a), Tenant shall have no right thereafter to rescind or elect not to extend the term of this Lease for the Extension Term.

(b) **Arbitration.**

(i) Within 10 days of Tenant’s notice to Landlord of its election (or deemed election) to arbitrate Market Rate and escalations, each party shall deliver to the other a proposal containing the Market Rate and escalations that the submitting party believes to be correct (“**Extension Proposal**”). If either party fails to timely submit an Extension Proposal, the other party’s submitted proposal shall determine the Base Rent and escalations for the Extension Term. If both parties submit Extension Proposals, then Landlord and Tenant shall meet within 7 days after delivery of the last Extension Proposal and make a good faith attempt to mutually appoint a single Arbitrator (and defined below) to determine the Market Rate and escalations. If Landlord and Tenant are unable to agree upon a single Arbitrator, then each shall, by written notice delivered to the other within 10 days after the meeting, select an Arbitrator. If either party fails to timely give notice of its selection for an Arbitrator, the other party’s submitted proposal shall determine the Base Rent for the Extension Term. The 2 Arbitrators so appointed shall, within 5 business days after their appointment, appoint a third Arbitrator. If the 2 Arbitrators so selected cannot agree on the selection of the third Arbitrator within the time above specified, then either party, on behalf of both parties, may request such appointment of such third Arbitrator by application to any state court of general jurisdiction in the jurisdiction in which the Premises are located, upon 10 days prior written notice to the other party of such intent.

(ii) The decision of the Arbitrator(s) shall be made within 30 days after the appointment of a single Arbitrator or the third Arbitrator, as applicable. The decision of the single Arbitrator shall be final and binding upon the parties. The average of the two closest Arbitrators in a three Arbitrator panel shall be final and binding upon the parties. Each party shall pay the fees and expenses of the Arbitrator appointed by or on behalf of such party and the fees and expenses of the third Arbitrator shall be borne equally by both parties. If the Market Rate and escalations are not

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determined by the first day of the Extension Term, then Tenant shall pay Landlord Base Rent in an amount equal to the Base Rent in effect immediately prior to the Extension Term and increased by the Rent Adjustment Percentage until such determination is made. After the determination of the Market Rate and escalations, the parties shall make any necessary adjustments to such payments made by Tenant. Landlord and Tenant shall then execute an amendment recognizing the Market Rate and escalations for the Extension Term.

(iii) An “**Arbitrator**” shall be any person appointed by or on behalf of either party or appointed pursuant to the provisions hereof and: (i) shall be (A) a member of the American Institute of Real Estate Appraisers with not less than 10 years of experience in the appraisal of improved life science and office space in the greater Boston, Massachusetts metropolitan area, or (B) a licensed commercial real estate broker with not less than 15 years’ experience representing landlords and/or tenants in the leasing of life sciences and office space in the greater Boston, Massachusetts metropolitan area, (ii) devoting substantially all of their time to professional appraisal or brokerage work, as applicable, at the time of appointment and (iii) be in all respects impartial and disinterested.

(c) **Rights Personal.** The Extension Rights are personal to Tenant and are not assignable without Landlord’s consent, which may be granted or withheld in Landlord’s sole discretion separate and apart from any consent by Landlord to an assignment of Tenant’s interest in this Lease, except that they may be assigned in connection with any Permitted Assignment of this Lease.

(d) **Exceptions.** Notwithstanding anything set forth above to the contrary, the Extension Rights shall, at Landlord’s option, not be in effect and Tenant may not exercise any of the Extension Rights:

(i) during any period of time that Tenant is in Default under any provision of this Lease; or

(ii) if Tenant has been in Default under any provision of this Lease 3 or more times, whether or not the Defaults are cured, during the 12 month period immediately prior to the date that Tenant intends to exercise an Extension Right, whether or not the Defaults are cured; or

(iii) if Tenant (or a transferee under a Permitted Assignment) is not in occupancy of at least 25% of the Premises demised hereunder both at the time of the exercise of any such Extension Right and at the time of the commencement date of any such Extension Term.

(e) **No Extensions.** The period of time within which any Extension Rights may be exercised shall not be extended or enlarged by reason of Tenant’s inability to exercise the Extension Rights.

(f) **Termination.** The Extension Rights shall, at Landlord’s option, terminate and be of no further force or effect even after Tenant’s due and timely exercise of an Extension Right, if, after such exercise, but prior to the commencement date of an Extension Term, (i) Tenant fails to timely cure any default by Tenant under this Lease; or (ii) Tenant has Defaulted 3 or more times during the period from the date of the exercise of an Extension Right to the date of the commencement of the Extension Term, whether or not such Defaults are cured.

**40. Exclusive Period.** If at any time during the term of this Lease, Tenant is considering leasing additional or alternative space, Tenant shall deliver written notice (“**Premises Notice**”) to Landlord, which Premises Notice shall include a description of the additional or alternative space desired by Tenant in the Commonwealth of Massachusetts. For a period of 30 days following Tenant’s delivery of the Premises Notice to Landlord (“**Exclusive Period**”), Tenant agrees that Landlord shall have the exclusive right, if it so elects and without any obligation to do so, to offer Tenant additional or alternative premises which satisfy in part or in its entirety the premises being sought by Tenant (“**Alternative Premises**”) on market terms at another property owned or controlled by Landlord or an entity controlled by, under common control with, or controlling Landlord including, without limitation, any of the constituent members of Landlord or Alexandria Real Estate Equities, Inc. (any such entity, an “**Affiliate**”). Landlord and/or any Affiliate, as the case may

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be, shall have the right, if it so elects and without any obligation to do so, to acquire a new project or redevelop any existing project it then owns to provide the Alternative Premises. Tenant shall be required to consider in good faith any Alternative Premises offered to Tenant by Landlord (or its Affiliate) during the Exclusive Period. If Landlord (or its Affiliate) and Tenant identify an Alternative Premises acceptable to Tenant, in Tenant's sole discretion, Landlord (or its Affiliate) and Tenant shall use good faith efforts to negotiate and enter into a new lease for such Alternative Premises. Such new lease shall, if entered into, be upon terms and conditions acceptable to Landlord or Affiliate, as the case may be, and Tenant in their respective good faith sole discretion. As part of Tenant's on-going real estate assessment, and to facilitate efficient engagement with Landlord with respect to any Premises Notice and any Exclusive Period, upon written request from Tenant (but not more than quarterly), Landlord will provide Tenant a summary of Landlord's available space in the Commonwealth of Massachusetts. The provisions of this paragraph shall only apply so long as ARE-MA Region No. 94, LLC, or an Affiliate is the owner of the Project. Nothing contained herein is intended to preclude Tenant from contacting real estate brokers during the Exclusive Period to seek information from such real estate brokers regarding their current experience regarding market terms for the Alternative Premises.

#### 41. Submarket Amenities.

(a) **Generally.** Subject to the provisions of this Section 41, one or more affiliates of Landlord (collectively, "**Amenity Affiliates**"), may construct certain common amenities (any such amenities, the

"**Submarket Amenities**") within the following geographical area surrounding the Project: Spring Street to the north, Atheneum Street to south, Third Street to the west and Edwin H Land Boulevard to the east (the "**Amenities Area**"), for non-exclusive use by tenants of (i) tenants of the projects owned or operated by any Amenity Affiliates, (ii) tenants of the Project, (iii) other affiliates of Landlord, Amenity Affiliates and Alexandria Real Estate Equities, Inc. ("**ARE**"), and (iv) any other parties permitted by Amenity Affiliates (collectively, "**Users**"). Landlord, Amenity Affiliates, ARE, and all affiliates of Landlord, Amenity Affiliates and ARE may be referred to collectively herein as the "**ARE Parties**." Any project within the Amenities Area at which Submarket Amenities are located may be referred to herein as a "**Submarket Amenities Project**." Notwithstanding anything to the contrary contained herein, Tenant acknowledges and agrees that the Amenity Affiliates shall have the right, in their sole respective discretion, to construct any Submarket Amenities desired by such Amenity Affiliates but not make all or a portion of such Submarket Amenities available for use by some or all currently contemplated Users. Amenity Affiliates shall, respectively have the sole right to determine all matters related to the Submarket Amenities including, without limitation, relating to the type, design and construction thereof. Tenant acknowledges and agrees that Landlord has not made any representations or warranties regarding the development of any of the Submarket Amenities and that Tenant is not entering into this Lease relying on the construction and completion of the Submarket Amenities or with an expectation that the Submarket Amenities will ever be constructed and/or made available to Tenant.

(b) **License.** Commencing on the date that any Submarket Amenities are made available for use by Users (the "**Amenities Commencement Date**"), and so long as the each applicable Submarket Amenities Project, respectively, continues to be owned by affiliates of ARE, Tenant shall have the non-exclusive right to the use of the available Submarket Amenities at such Submarket Amenities Project in common with other Users pursuant to the terms of this Section 41.

(c) **Submarket Amenities Fees.** Commencing on the Amenities Commencement Date, Tenant shall commence paying a fee equal to Tenant's Amenities Share. Tenant's "**Amenities Share**" shall be an amount equal to Tenant's share of the Submarket Amenities Costs, which shall be equal to a percentage of the Submarket Amenities Costs calculated by dividing the rentable square footage of the Premises by the rentable square footage of all Users granted the right under their respective leases (or other applicable occupancy agreement(s)) to all or portion of the Submarket Amenities. In no event shall the Amenities Share include any costs or expenses for any portion of the Submarket Amenities which Tenant does not have a right to use. As used in this Lease, "**Submarket Amenities Costs**" shall mean all costs and expenses of any kind or description whatsoever incurred or accrued each calendar year with respect to the operation of the Submarket Amenities (including for the avoidance of doubt, reimbursement by Amenities

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Affiliates to affiliates of such Amenities Affiliates for market rent paid by such affiliates to Amenities Affiliates for Submarket Amenities space and commercially reasonable reduced rent or other commercially reasonable concessions or subsidies provided in connection with the Submarket Amenities) that would have been payable with respect to the space in which the Submarket Amenities are located had they had been leased to third parties), not including costs or expenses in connection with the design or construction of the Submarket Amenities or the cost of correcting defects in the construction of the Submarket Amenities, which costs and expenses shall not be passed through to Tenant.

Notwithstanding the foregoing, for the period during the Base Term commencing on the Amenities Commencement Date through the expiration of the first full calendar year following the Amenities Commencement Date, Tenant shall not be responsible for Tenant's Amenities Share of Submarket Amenities Costs in excess of \$2.25 per rentable square foot of the Premises per year (the "**Cap Amount**"). The Cap Amount shall increase on each January 1<sup>st</sup> thereafter during the Base Term by multiplying the Cap Amount applicable during the immediately preceding calendar year by 3% and adding the resulting amount to the Cap Amount applicable during the immediately preceding calendar year. For the avoidance of doubt, the cost of Submarket Amenities Costs subject to the Cap Amount shall not include costs relating to Shuttle Service or the cost of ancillary services or items payable by Tenant in connection with its use of the Submarket Amenities which may include without limitation, conference center booking fees (to the extent one or more conference centers are included as part of the Submarket Amenities), costs for food and beverage/catering services, personal training, fitness classes and/or wellness clinics.

(d) **Rules and Regulations.** Tenant shall be solely responsible for paying the cost of any and all ancillary services provided to Tenant, and the cost of any and all goods and services provided to Tenant by any food services operators and/or any third party vendors in connection with Tenant's use of the Submarket Amenities. Tenant shall use the Submarket Amenities in compliance with all applicable Legal Requirements and any reasonable rules and regulations imposed by the applicable Amenities Affiliate from time to time and in a manner that will not interfere with the rights of other Users, which rules and regulations shall be enacted and enforced in a non-discriminatory manner and may include, (i) the required use by Users of one or more food and beverage operators designated by the applicable Amenities Affiliate, (ii) usage of and compliance with reservations systems governing the use of facilities, (iii) the payment of additional costs in connection with the after-hours usage of facilities, and (iv) access card entry requirements. The use of the Submarket Amenities by employees of Tenant shall be in accordance with the terms and conditions of the standard licenses, indemnification and waiver agreements required by applicable Amenities Affiliate or the operator of the applicable Submarket Amenities to be executed by all persons wishing to use such Submarket Amenities. Neither the Amenities Affiliates nor Landlord (nor, if applicable, any other affiliate of Landlord) shall have any liability or obligation for the breach of any rules or regulations by other Users with respect to the Submarket Amenities. Tenant shall not make any alterations, additions, or improvements of any kind to the Submarket Amenities or any Submarket Amenities Project.

Tenant acknowledges and agrees that the Amenities Affiliates shall have the right at any time and from time to time to reconfigure, relocate, modify or remove any of the Submarket Amenities, and/or to revise, expand or discontinue any of the services (if any) provided in connection with the Submarket Amenities.

(e) **Waiver of Liability and Indemnification.** Tenant warrants that it will use reasonable care to prevent damage to property and injury to persons while on any project at each respective Submarket Amenities Project. Tenant waives any claims it or any Tenant Parties may have against any ARE Parties relating to, arising out of or in connection with the Submarket Amenities and any entry by Tenant and/or any Tenant Parties onto any Submarket Amenities Project, and Tenant releases and exculpates all ARE Parties from any liability relating to, arising out of or in connection with the Submarket Amenities and any entry by Tenant and/or any Tenant Parties onto each Submarket Amenities Project. Tenant hereby agrees to indemnify, defend, and hold harmless the ARE Parties from any claim of damage to property or injury to persons relating to, arising out of or in connection with (i) the use of the Submarket Amenities by Tenant or any Tenant Parties, and (ii) any entry by Tenant and/or any Tenant Parties onto any Submarket Amenities Project, except to the extent caused by the negligence or willful misconduct of ARE Parties. The provisions of this Section 41(e) shall survive the expiration or earlier termination of this Lease.

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**42. Miscellaneous.**

(a) **Notices.** All notices or other communications between the parties shall be in writing and shall be deemed duly given upon delivery or refusal to accept delivery by the addressee thereof if delivered in person, or upon actual receipt if delivered by reputable overnight guaranty courier, addressed and sent to the parties at their addresses set forth above. Landlord and Tenant may from time to time by written notice to the other designate another address for receipt of future notices. For the avoidance of doubt, Landlord's agreement to deliver copies of notices to Tenant via email is a courtesy basis only and the failure of Landlord to deliver copies of any such notices to Tenant via email shall in no event invalidate or otherwise affect the effectiveness of any notice delivered to Tenant in accordance with the requirements of this Section 42(a).

(b) **Joint and Several Liability.** If and when included within the term "**Tenant**," as used in this instrument, there is more than one person or entity, each shall be jointly and severally liable for the obligations of Tenant.

(c) **Financial Information.** Tenant shall furnish to Landlord with true and complete copies of (i) upon Landlord's written request on an annual basis, Tenant's most recent audited annual financial statements, provided, however, that Tenant shall not be required to deliver to Landlord such annual financial statements for any particular year sooner than the date that is 90 days after the end of each of Tenant's fiscal years during the Term, (ii) upon Landlord's written request on a quarterly basis, Tenant's most recent unaudited quarterly financial statements; provided, however, that Tenant shall not be required to deliver to Landlord such quarterly financial statements for any particular quarter sooner than the date that is 45 days after the end of each of Tenant's fiscal quarters during the Term, (iii) upon Landlord's written request from time to time, updated business plans, including cash flow projections and/or pro forma balance sheets and income statements, all of which shall be treated by Landlord as confidential information belonging to Tenant, (iv) upon Landlord's written request from time to time, corporate brochures and/or profiles prepared by Tenant for prospective investors, and (v) upon Landlord's written request from time to time, any other financial information or summaries that Tenant typically provides to its lenders or shareholders. Notwithstanding anything to the contrary contained in this Lease, Landlord's written request for financial information pursuant to this Section 42(c) may be delivered to Tenant via email. So long as Tenant is a "public company" and its financial information is publicly available, then the foregoing delivery requirements of this Section 42(c) shall not apply.

(d) **Recordation.** Neither this Lease nor a memorandum of lease shall be filed by or on behalf of Tenant in any public record. Landlord may prepare and file, and upon request by Landlord Tenant will execute, a memorandum of lease. Nothing contained in this Lease is intended to prohibit Tenant from filing this Lease with the Securities and Exchange Commission ("**SEC**") to the extent that Tenant is required to do so pursuant to applicable SEC requirements. Prior to any such filing of this Lease, Tenant shall redact the Base Rent and other economic terms to the extent permitted by applicable SEC regulations.

(e) **Interpretation.** The normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Lease or any exhibits or amendments hereto. Words of any gender used in this Lease shall be held and construed to include any other gender, and words in the singular number shall be held to include the plural, unless the context otherwise requires. The captions inserted in this Lease are for convenience only and in no way define, limit or otherwise describe the scope or intent of this Lease, or any provision hereof, or in any way affect the interpretation of this Lease.

(f) **Not Binding Until Executed.** The submission by Landlord to Tenant of this Lease shall have no binding force or effect, shall not constitute an option for the leasing of the Premises, nor confer any right or impose any obligations upon either party until execution of this Lease by both parties.

(g) **Limitations on Interest.** It is expressly the intent of Landlord and Tenant at all times to comply with applicable law governing the maximum rate or amount of any interest payable on or in

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connection with this Lease. If applicable law is ever judicially interpreted so as to render usurious any interest called for under this Lease, or contracted for, charged, taken, reserved, or received with respect to this Lease, then it is Landlord's and Tenant's express intent that all excess amounts theretofore collected by Landlord be credited on the applicable obligation (or, if the obligation has been or would thereby be paid in full, refunded to Tenant), and the provisions of this Lease immediately shall be deemed reformed and the amounts thereafter collectible hereunder reduced, without the necessity of the execution of any new document, so as to comply with the applicable law, but so as to permit the recovery of the fullest amount otherwise called for hereunder.

(h) **Choice of Law.** Construction and interpretation of this Lease shall be governed by the internal laws of the Commonwealth of Massachusetts, excluding any principles of conflicts of laws.

(i) **Time.** Time is of the essence as to the performance of Tenant's obligations under this Lease.

(j) **OFAC.** Tenant and, to Tenant's knowledge, all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("OFAC") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of this Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

(k) **Incorporation by Reference.** All exhibits and addenda attached hereto are hereby incorporated into this Lease and made a part hereof. If there is any conflict between such exhibits or addenda and the terms of this Lease, such exhibits or addenda shall control.

(l) **Entire Agreement.** This Lease, including the exhibits attached hereto, constitutes the entire agreement between Landlord and Tenant pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, understandings, letters of intent, negotiations and discussions, whether oral or written, of the parties, and there are no warranties, representations or other agreements, express or implied, made to either party by the other party in connection with the subject matter hereof except as specifically set forth herein.

(m) **No Accord and Satisfaction.** No payment by Tenant or receipt by Landlord of a lesser amount than the monthly installment of Base Rent or any Additional Rent will be other than on account of the earliest stipulated Base Rent and Additional Rent, nor will any endorsement or statement on any check or letter accompanying a check for payment of any Base Rent or Additional Rent be an accord and satisfaction. Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or to pursue any other remedy provided in this Lease.

(n) **Hazardous Activities.** Notwithstanding any other provision of this Lease, Landlord, for itself and its employees, agents and contractors, reserves the right to refuse to perform any repairs or services in any portion of the Premises which, pursuant to Tenant's routine safety guidelines, practices or custom or prudent industry practices, require any form of protective clothing or equipment other than safety glasses. In any such case, Tenant shall contract with parties who are acceptable to Landlord, in Landlord's reasonable discretion, for all such repairs and services, and Landlord shall, to the extent required, equitably adjust Tenant's Share of Operating Expenses in respect of such repairs or services to reflect that Landlord is not providing such repairs or services to Tenant.

(o) **Redevelopment of Project.** Tenant acknowledges that Landlord, in its sole discretion, may, subject to the terms of the penultimate sentence of Section 1 of this Lease, from time to time expand, renovate and/or reconfigure the Project as the same may exist from time to time and, in connection therewith or in addition thereto, as the case may be, from time to time without limitation: (a) change the shape, size, location, number and/or extent of any improvements, buildings, structures, lobbies, hallways,

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entrances, exits, parking and/or parking areas relative to any portion of the Project; (b) modify, eliminate and/or add any buildings, improvements, and parking structure(s) either above or below grade, to the Project, the Common Areas and/or any other portion of the Project and/or make any other changes thereto affecting the same; and (c) make any other changes, additions and/or deletions in any way affecting the Project and/or any portion thereof as Landlord may elect from time to time, including without limitation, additions to and/or deletions from the land comprising the Project, the Common Areas and/or any other portion of the Project. Tenant acknowledges and agrees that construction noise, vibrations and dust associated with normal construction activities in connection with any redevelopment of the Project are to be expected during the course of such construction. Notwithstanding anything to the contrary contained in this Lease, Tenant shall have no right to seek damages (including abatement of Rent) or to cancel or terminate this Lease because of any proposed changes, expansion, renovation or reconfiguration of the Project nor shall Tenant have the right to restrict, inhibit or prohibit any such changes, expansion, renovation or reconfiguration; provided, however, Landlord shall not change the size, dimensions, location or Tenant's Permitted Use of the Premises.

(p) **Shuttle.** Landlord and affiliates of Landlord plan to provide a campus shuttle service for the Project and other buildings in the vicinity of the Project that are owned by affiliates of Landlord (the "**Shuttle Service**"); provided, however, that neither Landlord nor any affiliate of Landlord shall be obligated to provide the Shuttle Service (or, once the Shuttle Service has commenced, to continue providing the Shuttle Service for any specific period of time) or to cause the Shuttle Service to follow any specific route, make any specific stops, or adhere to any specific schedule or hours of operation. If Landlord and affiliates of Landlord actually commence operation of the Shuttle Service, (i) Landlord shall give Tenant written notice of the date such operation will commence ("**Shuttle Services Commencement Date**") and the planned route, stops, schedule, and hours of operation, (ii) Landlord shall permit Tenant's employees actually employed at the Project to use the Shuttle Service, and (iii) regardless of whether Tenant's employees use the Shuttle Services, commencing on later to occur of (x) the Shuttle Services Commencement Date, or the Commencement Date, through the earlier of the expiration of the Term or the date that Landlord permanently ceases to provide Shuttle Service, Operating Expenses shall include the cost of provision the Shuttle Service (the "**Shuttle Service Costs**"). Tenant acknowledges and agrees that Landlord has not made any representations or warranties regarding the commencement or continued availability of the Shuttle Service and that Tenant is not entering into this Lease with an expectation that the Shuttle Service shall commence or continue to be available to Tenant throughout the Term.

(q) **Counterparts.** This Lease may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Lease and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

[ Signatures on next page ]

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**Net Multi-Tenant Laboratory**

**One Charles Park – Suite 501/Omega Therapeutics - Page 44**

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease as of the day and year first above written.

**TENANT:**

**OMEGA THERAPEUTICS, INC.,**  
a Delaware corporation

By: /s/ Mahesh Karande  
Its: President and CEO

X I hereby certify that the signature, name, and title above are my signature, name and title.

**LANDLORD:**

**ARE-MA REGION NO. 94, LLC,**  
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,  
a Delaware limited partnership,  
managing member

By: ARE-QRS CORP.,  
a Maryland corporation  
general partner

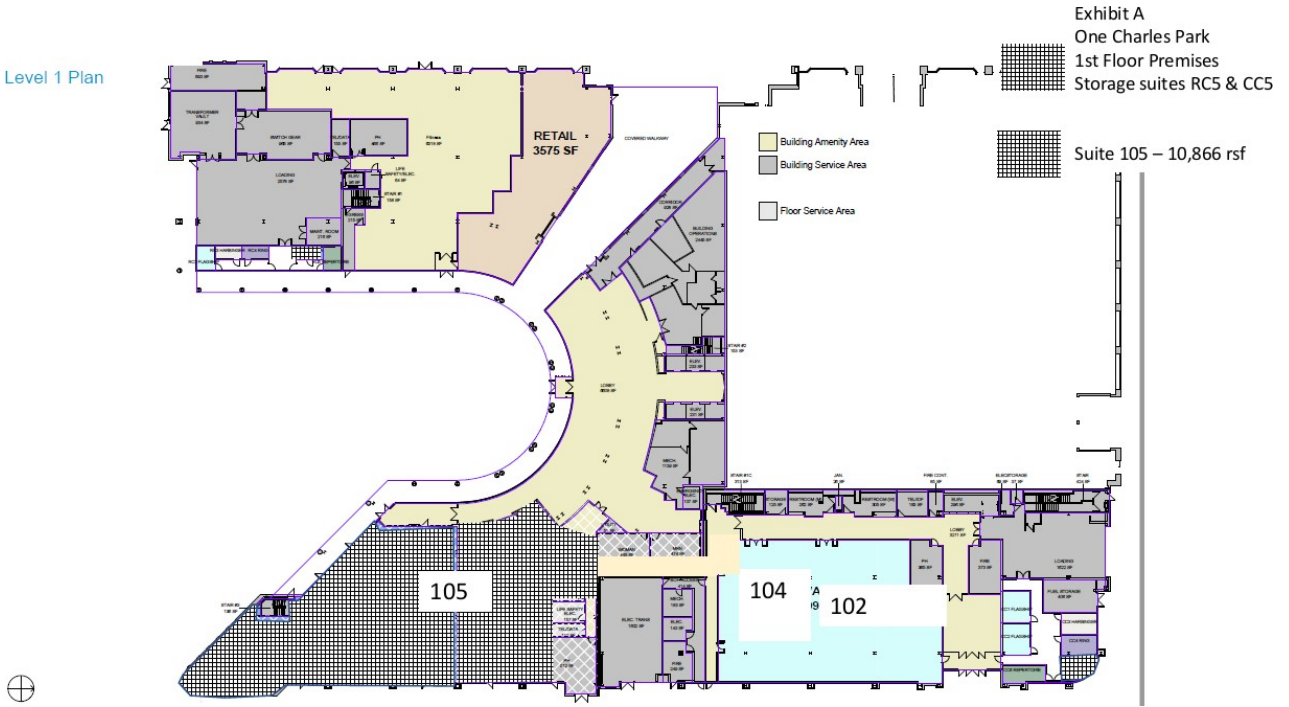
By: /s/ Allison Grochola  
Print name: Allison Grochola  
Title: SVP - Real Estate Legal Affairs

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EXHIBIT A TO LEASE

DESCRIPTION OF PREMISES

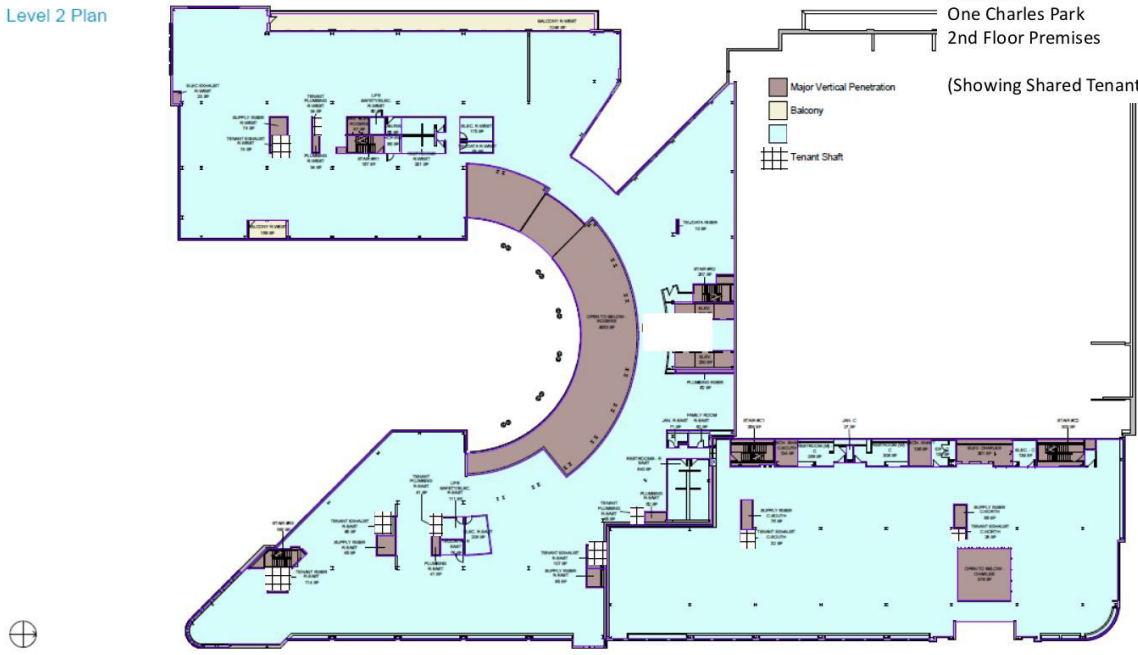
Level 1 Plan



Level 2 Plan

Exhibit A  
One Charles Park  
2nd Floor Premises

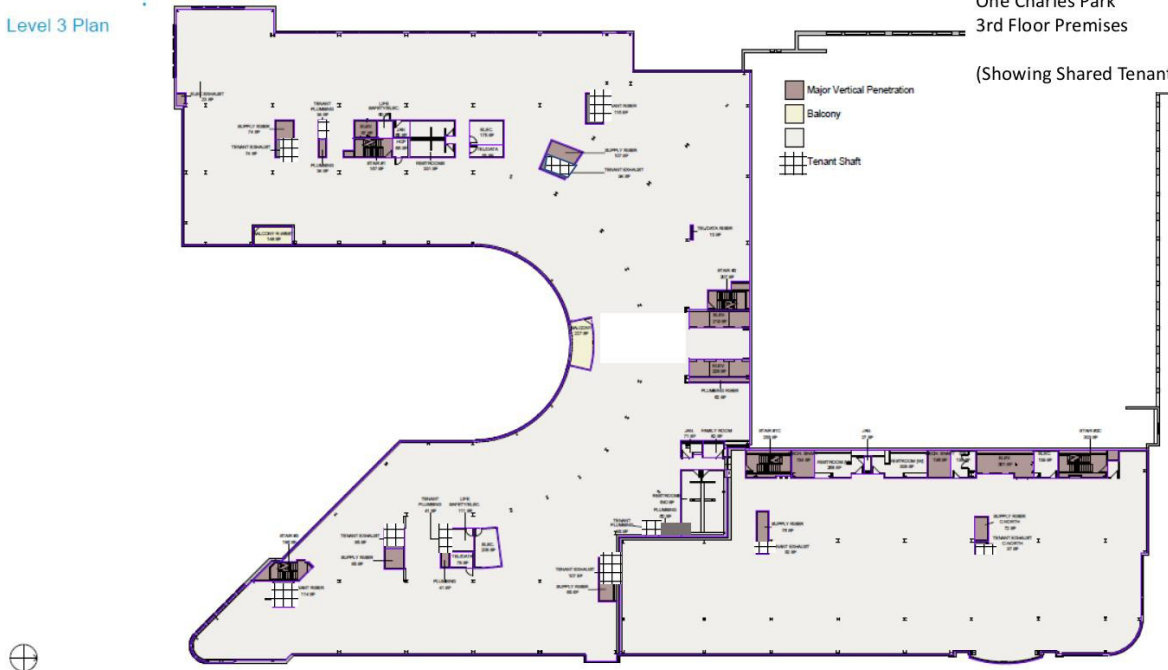
(Showing Shared Tenant Shafts)



Level 3 Plan

Exhibit A  
One Charles Park  
3rd Floor Premises

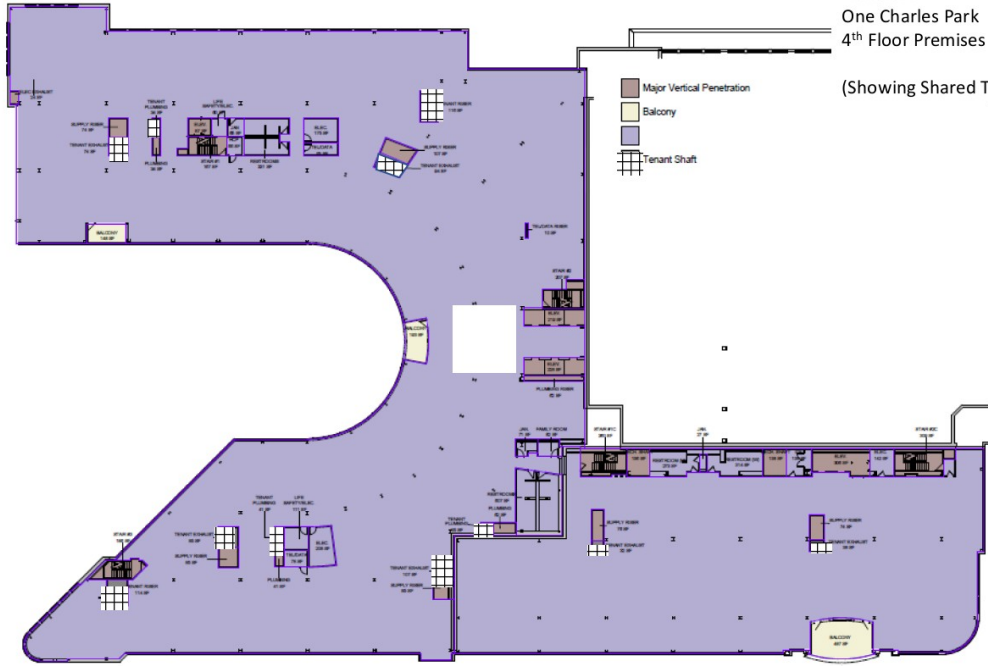
(Showing Shared Tenant Shafts)



Level 4 Plan

Exhibit A  
One Charles Park  
4<sup>th</sup> Floor Premises

(Showing Shared Tenant Shafts)



Level 5 Plan

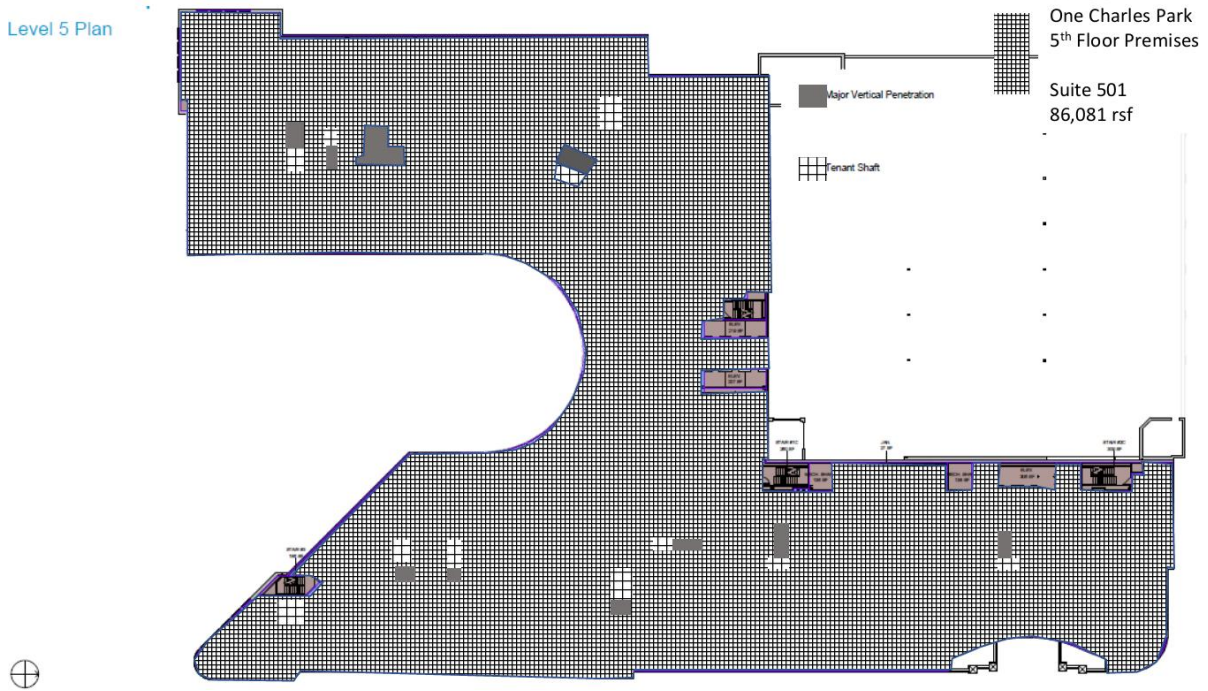


Exhibit A  
One Charles Park  
5<sup>th</sup> Floor Premises

Suite 501  
86,081 rsf



Level 6 Plan

Exhibit A  
One Charles Park  
6<sup>th</sup> Floor Premises  
(Showing Shared Tenant Shaft)

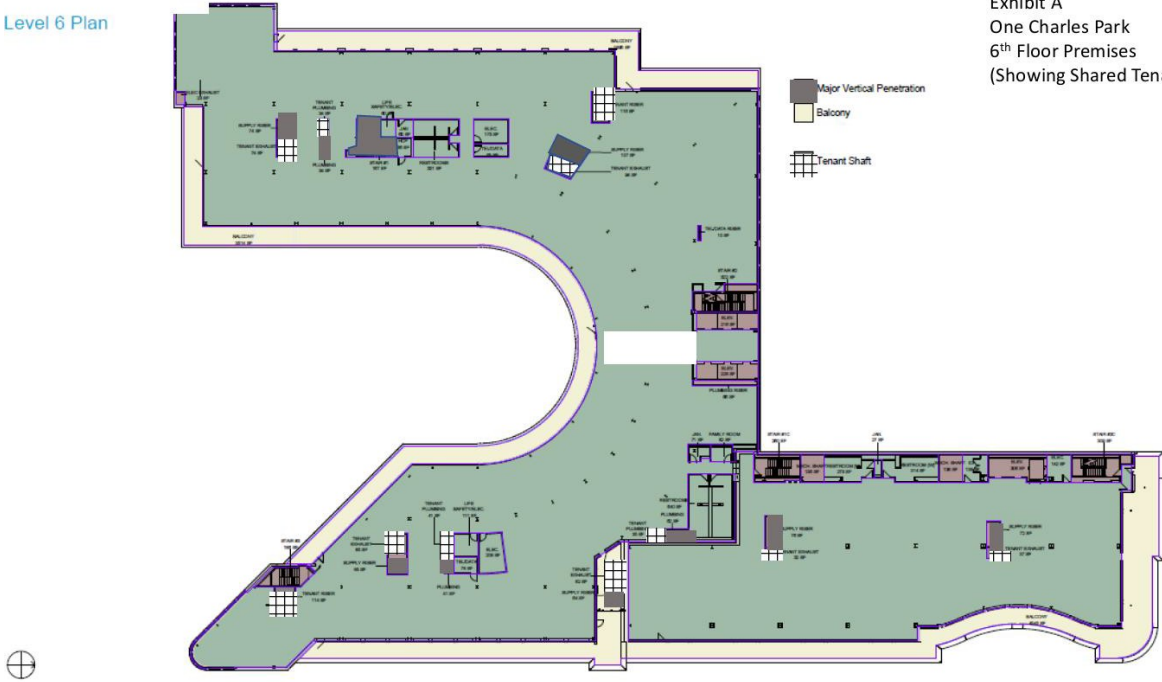


Exhibit A  
One Charles Park  
Penthouse Level  
Premises PH5

Mechanical Level

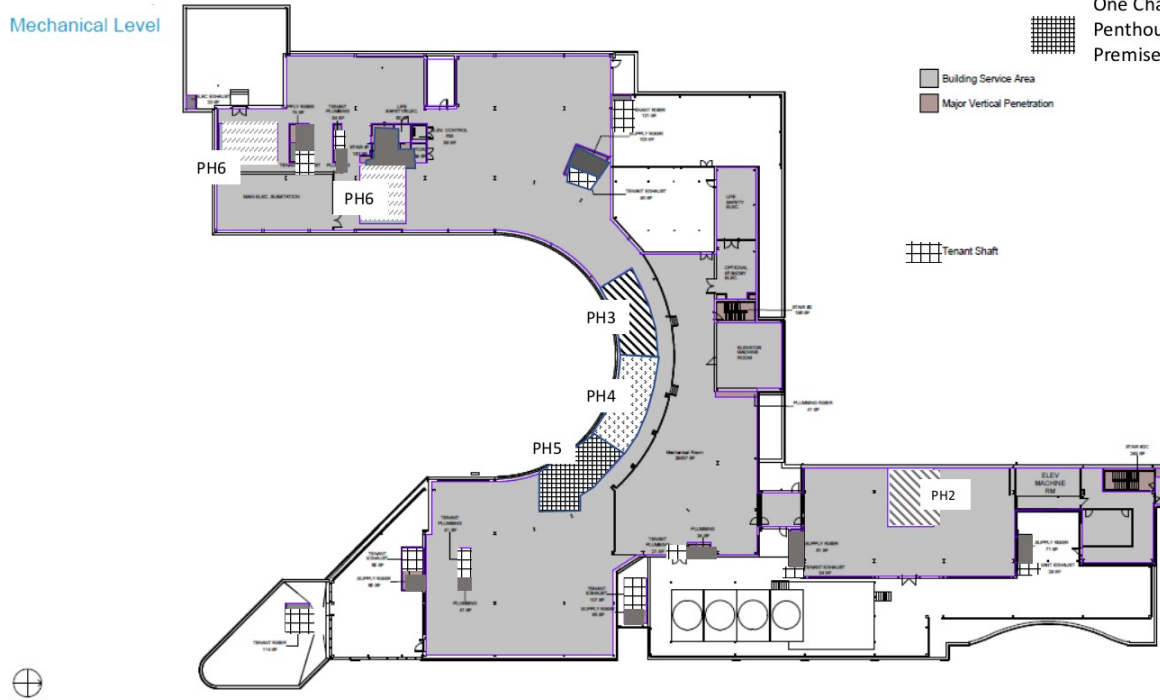


EXHIBIT B TO LEASE

**DESCRIPTION OF PROJECT**

ONE CHARLES PARK

Real property in the County of Middlesex, Commonwealth of Massachusetts, described as follows:

That certain parcel of land in Cambridge, Middlesex County, Massachusetts, shown as Lot 41 on [Land Court Plan No. 85Z](#).

All of said boundaries are determined by the Court to be located as shown on a subdivision plan, as approved by the Court, filed in the Land Registration Office, a copy of which is filed in the Registry of Deeds for the South Registry District of Middlesex County in Registration Book 1073, Page 150, with Certificate 188700.

APPURTENANT RIGHTS

1. Grant of Easement from the Trustee of River Court Development Trust to the Trustees of Riverside Galleria Associates Trust dated November 21, 1988 filed as [Document No. 779978](#).
  2. Rights and easements reserved in instruments filed as [Documents 796204, 796206](#) and [799293](#), as affected by Modification Agreement between the Trustees of CambridgeSide Galleria Associates Trust and Trustees of CambridgeSide Residential Associates Trust dated May 31, 1990 filed as [Document No. 823185](#).
  3. Grant of Easement from the City of Cambridge to CambridgeSide Galleria Associates Trust dated March 6, 1989 filed as [Document No. 796215](#) and recorded in Book 19732, Page 593.
  4. Tieback and Indemnity Agreement from Trustees of Edgewater Place Limited Partnership to Trustees of CambridgeSide Galleria Associates Trust filed as [Document No. 798414](#) and recorded in Book 19802, Page 279.
  5. Grant of Easement from Lotus Development Corporation to the Trustees of CambridgeSide Galleria Associates Trust dated August 28, 1989 filed as [Document No. 808696](#).
  6. Grant of Easement to construct and maintain underground system from Lotus Development Corporation to the Trustees of CambridgeSide Galleria Associates Trust dated August 28, 1989 filed as [Document No. 808697](#).
  7. Leasehold rights as tenant to leased parking spaces as found under an unrecorded Indenture of Lease by and between Stephen R. Karp and Robert Burrill, as Trustees of CambridgeSide Galleria Associates Trust, as Landlord, Lotus Charles Park Corporation, as Tenant, filed as [Document No. 1251372](#) and recorded in Book 37863, Page 231, as affected by Assignment and Assumption of Parking Exchange Agreement by and between International Business Machines
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Corporation, as Assignor, and Rogers Park 2002 LLC, as Assignee filed as [Document No.1280782](#) and recorded in Book 39803, Page 592.

8. Parking Area Use and Easement Agreement by and between One Charles Park, LLC and Rogers Park 2002, LLC filed as [Document No.1348017](#) and recorded in Book 43665, Page 1.

#### ONE ROGERS STREET

Real property in the County of Middlesex, Commonwealth of Massachusetts, described as follows:

##### Parcel I

That certain parcel of land in Cambridge, Middlesex County, Massachusetts, shown as Lot 39 on [Land Court Plan No. 85y](#).

All of said boundaries are determined by the Court to be located as shown on a subdivision plan, as approved by the Court, filed in the Land Registration Office, a copy of which is filed in the Registry of Deeds for the South Registry District of Middlesex County in Registration Book 1062, Page 118, with Certificate 186468.

##### Parcel II

That certain parcel of land in Cambridge, Middlesex County, Massachusetts shown as Lot A on a plan entitled, "Easement Plan of Land in Cambridge, Mass." Dated July 18, 1989 drawn by Ryan Engineering Corp. and recorded with the Middlesex South District Registry of Deeds in Book 20128, Page 520 as [Plan 1129 of 1989](#).

#### APPURTENANT RIGHTS

1. Grant of Easement and Agreement for light and air dated August 28, 1989 from the Trustees of CambridgeSide Galleria Associates Trust to Lotus Development Corporation recorded with said Registry of Deeds in Book 20128, Page 534 and filed with said Registry District as [Document 808698](#).

2. Reservations of rights and easements set forth in the deed from Lotus Development Corporation to the City of Cambridge, dated August 28, 1989 and recorded with said Registry of Deeds in Book 20268, Page 277 and filed with said Registered Land District as [Document No. 808700](#).

3. Parking Exchange Agreement by and among Warburton Corporation and International Business Machines Corporation, dated January 29, 2003 and recorded with the Middlesex Southern District Registered Land District on January 31, 2003 as [Document No. 1251372](#) and in Book 37863, Page 231, as affected by an Assignment and Assumption of Parking Exchange Agreement by and between International Business Machines Corporation, as Assignor, and Rogers Park 2002 LLC, as Assignee; recorded with the Middlesex South Registry of Deeds on

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July 3, 2003 in Book 39803, Page 592 and with the Middlesex South Registry of Deeds Registered Land District as [Document No. 1280782](#).

NOTE: As used herein, "filed" shall mean "filed with the Middlesex South Registry District of the Land Court" and "recorded" shall mean "recorded in the Middlesex South Registry of Deeds".

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**EXHIBIT C TO LEASE WORK**

**LETTER**

THIS WORK LETTER dated November 4, 2021 (this "**Work Letter**") is made and entered into by and between **ARE-MA REGION NO. 94, LLC**, a Delaware limited liability company ("**Landlord**"), and **OMEGA THERAPEUTICS, INC.**, a Delaware corporation ("**Tenant**"), and is attached to and made a part of the Lease Agreement dated November 4, 2021 (the "**Lease**"), by and between Landlord and Tenant. Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

1. **General Requirements.**

(a) **Tenant's Authorized Representative.** Tenant designates Al Vaz ("**Tenant's Representative**") as the only persons authorized to act for Tenant pursuant to this Work Letter. Landlord shall not be obligated to respond to or act upon any request, approval, inquiry or other communication ("**Communication**") from or on behalf of Tenant in connection with this Work Letter unless such Communication is in writing from Tenant's Representative. Tenant may change Tenant's Representative at any time upon not less than 2 business days advance written notice to Landlord, which notice may be delivered via email. The email address for Tenant's Representative named in this Section 1(a) is avaz@fsplabs.com. Neither Tenant nor Tenant's Representative shall be authorized to direct Landlord's contractors in the performance of Landlord's Work (as hereinafter defined).

(b) **Landlord's Authorized Representative.** Landlord designates Tim White and Jeff Cook (either such individual acting alone, "**Landlord's Representative**") as the only persons authorized to act for Landlord pursuant to this Work Letter. Tenant shall not be obligated to respond to or act upon any request, approval, inquiry or other Communication from or on behalf of Landlord in connection with this Work Letter unless such Communication is in writing from Landlord's Representative. Landlord may change either Landlord's Representative at any time upon not less than 2 business days advance written notice to Tenant, which notice may be delivered via email. The email addresses for Landlord's Representatives named in this Section 1(b) are twhite@are.com and jcook@are.com. Landlord's Representative shall be the sole persons authorized to direct Landlord's contractors in the performance of Landlord's Work.

(c) **Architects, Consultants and Contractors.** Landlord and Tenant hereby acknowledge and agree that: (i) Commodore Construction shall be the general contractor for the Tenant Improvements (the "**General Contractor**"), (ii) SGA shall be the architect (the "**TI Architect**") for the Tenant Improvements, and (iii) and any subcontractors for the Tenant Improvements shall be selected by Landlord, subject to Tenant's approval, which approval shall not be unreasonably withheld, conditioned or delayed. Tenant shall have the right to retain a third party project manager reasonably acceptable to Landlord ("**Project Manager**") to provide project management services to Tenant in connection with the Tenant Improvements.

(d) **Construction Contract.** The contract for construction of the Tenant Improvements shall be written substantially on Landlord's standard form of construction agreement with modifications reasonably acceptable to Landlord where the contract sum is the costs of the work plus a fee not to exceed a "Guaranteed Maximum Price" equal to the dollar amount set forth in the Approved Budget (as defined in Section 5(a)) (which Approved Budget shall be based upon completed permit drawings and shall not include comments raised by Governmental Authorities as part of their permit review) subject to the terms of such contract and subject to any increases resulting from Changes and any changes to the permit drawings required by Governmental Authorities implemented after approval of the Approved Budget.

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2. **Tenant Improvements.**

(a) **Tenant Improvements Defined.** As used herein, “**Tenant Improvements**” shall mean all improvements to the Premises of a fixed and permanent nature as shown on the TI Construction Drawings, as defined in Section 2(c) below. Other than Landlord’s Work (as defined in Section 3(a) below, Landlord shall not have any obligation whatsoever with respect to the finishing of the Premises for Tenant’s use and occupancy.

(b) **Tenant’s Space Plans.** Tenant shall promptly deliver to Landlord schematic drawings and outline specifications (the “**Space Plans**”) for the Tenant Improvements. To the extent that the Space Plans do not reflect the requirements of Tenant for the Tenant Improvements as discussed in the applicable Project Meetings (as defined in Section 2(e) below), which Project Meetings shall be held no less frequently than weekly until the Space Plans have been finalized, Tenant shall promptly deliver to Landlord written feedback to the Space Plans, Landlord shall consider such feedback from Tenant in good faith and, if applicable, the Space Plans shall be revised accordingly. Landlord and Tenant shall proceed collaboratively, including at Project Meetings, to advance the Space Plans until they have been approved by Landlord and Tenant. Notwithstanding anything to the contrary contained herein, Tenant shall be solely responsible for ensuring that the Space Plans reflect Tenant’s requirements for the Tenant Improvements.

(c) **Working Drawings.** Landlord shall cause the TI Architect to prepare and deliver to Tenant for review and comment construction plans, specifications and drawings for the Tenant Improvements (“**TI Construction Drawings**”) within 10 business days after Landlord and Tenant have approved the Space Plans, which TI Construction Drawings shall be prepared substantially in accordance with the Space Plans. Tenant shall be solely responsible for ensuring that the TI Construction Drawings reflect Tenant’s requirements for the Tenant Improvements as discussed in the applicable Project Meetings. To the extent that the TI Construction Drawings are not consistent with the Space Plans, Tenant shall promptly deliver to Landlord written feedback to the TI Construction Drawings, Landlord shall consider such feedback from Tenant in good faith and, if applicable, the TI Construction Drawings shall be revised accordingly. Landlord and Tenant shall proceed collaboratively, including at Project Meetings, to advance the TI Construction Drawings until they have been approved by Landlord and Tenant. Tenant may not disapprove any matter that is consistent with the finalized Space Plans without submitting a Change Request (as defined in Section 4), which Change Request shall be subject to the terms of Section 4. Any disputes in connection with such comments shall be resolved in accordance with Section 2(d) hereof. Once approved by Landlord and Tenant, subject to the provisions of Section 4 below, Landlord shall not materially modify the TI Construction Drawings except as may be reasonably required in connection with the issuance of the TI Permit (as defined in Section 3(b) below).

(d) **Approval and Completion.** It is hereby acknowledged by Landlord and Tenant that the TI Construction Drawings for the Phase 1 Premises (as defined in the Lease) must be finalized by January 15, 2022, in order for Landlord’s Work in the Phase 1 Premises to be Substantially Complete by the Phase 1 Target Commencement Date (as defined in the Lease) and the failure of the TI Construction Drawings for the Phase 1 Premises to be finalized by such date shall constitute a Tenant Delay. It is hereby further acknowledged by Landlord and Tenant that the TI Construction Drawings for the Phase 2 Premises (as defined in the Lease) must be finalized by March 15, 2022, in order for Landlord’s Work in the Phase 2 Premises to be Substantially Complete by the Phase 2 Target Commencement Date (as defined in the Lease) and the failure of the TI Construction Drawings for the Phase 2 Premises to be finalized by such date shall constitute a Tenant Delay. Upon any dispute regarding the design of the Tenant Improvements, which is not settled within 10 business days after notice of such dispute is delivered by one party to the other, Tenant may make the final decision regarding the design of the Tenant Improvements, provided (i) Tenant acts reasonably and such final decision is either consistent with or a compromise between Landlord’s and Tenant’s positions with respect to such dispute, (ii) that all costs and expenses resulting from any such decision by Tenant shall be payable out of the TI Fund (as defined in Section 5(d) below), and (iii) Tenant’s decision will not affect the base Building, structural components of the Building or any Building systems. Any changes to the TI Construction Drawings following Landlord’s and Tenant’s approval of same requested by Tenant shall be processed as provided in Section 4 hereof. The parties shall develop

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**Work Letter – Tenant Build**

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a schedule for the construction of the Tenant Improvements following the finalization of the TI Construction Drawings.

(e) **Project Meetings.** The parties will hold regular project meetings (each, a “**Project Meeting**”) to, among other things, (i) review design documents relating to Tenant Improvements, and (ii) review the progress of the design and construction of the Tenant Improvements, and (iii) observation of the status of construction of the Tenant Improvements. Any such observation shall be conducted under the supervision of the General Contractor and shall be subject to the General Contractor’s rules and safety requirements. The Project Meetings shall be attended by Landlord’s Representative, Tenant’s Representative, the General Contractor and the TI Architect, and other appropriate members of the design and construction team (as appropriate given the time and subject of the particular Project Meeting).

**3. Performance of Landlord’s Work.**

(a) **Definition of Landlord’s Work.** As used herein, “**Landlord’s Work**” shall mean (i) the work of constructing the Tenant Improvements which shall be paid for out of the TI Fund, and (ii) the construction of the base building work identified on the Landlord/Tenant Responsibility Matrix attached hereto as **Schedule 1** as being Landlord’s responsibility (the “**Base Building Improvements**”), which Base Building Improvements shall be performed at Landlord’s cost. The anticipated schedule for Landlord’s design and construction of the Base Building Improvements is attached hereto as **Schedule 2**.

Tenant shall be solely responsible for ensuring that the design and specifications for Landlord’s Work are consistent with Tenant’s requirements. Landlord shall be responsible for obtaining all permits, approvals and entitlements necessary for Landlord’s Work, but shall have no obligation to, and shall not, secure any permits, approvals or entitlements related to Tenant’s specific use of the Premises or Tenant’s business operations therein.

(b) **Commencement and Permitting.** Landlord shall commence construction of the Tenant Improvements upon obtaining a building permit (the “**TI Permit**”) authorizing the construction of the Tenant Improvements consistent with the TI Construction Drawings approved by Tenant. The cost of obtaining the TI Permit shall be payable from the TI Fund. Tenant shall assist Landlord in obtaining the TI Permit. If any Governmental Authority having jurisdiction over the construction of Landlord’s Work or any portion thereof shall impose terms or conditions upon the construction thereof that: (i) are inconsistent with Landlord’s obligations hereunder, (ii) materially increase the cost of constructing Landlord’s Work, or (iii) will materially delay the construction of Landlord’s Work, Landlord and Tenant shall reasonably and in good faith seek means by which to mitigate or eliminate any such adverse terms and conditions.

(c) **Completion of Landlord’s Work.** Landlord shall substantially complete or cause to be substantially completed Landlord’s Work in a good and workmanlike manner and in accordance with applicable Legal Requirements, in accordance with the TI Permit subject, in each case, to Minor Variations and normal “punch list” items of a non-material nature that do not interfere with the use of the Phase 1 Premises or the Phase 2 Premises, respectively (“**Substantial Completion**” or “**Substantially Complete**”). Notwithstanding the foregoing, Landlord’s Work shall not be considered Substantially Complete unless and until Landlord has obtained a certificate of occupancy or temporary certificate of occupancy (or an equivalent approval having been issued) for the Phase 1 Premises or the Phase 2 Premises, as applicable, permitting lawful occupancy of the Phase 1 Premises or Phase 2 Premises, as applicable (but specifically excluding any permits, licenses or other governmental approvals required to be obtained in connection with Tenant’s operations in the Premises). Upon Substantial Completion of Landlord’s Work, Landlord shall require the TI Architect and the General Contractor to execute and deliver, for the benefit of Tenant and Landlord, a Certificate of Substantial Completion in the form of the American Institute of Architects (“**AIA**”) document G704. For purposes of this Work Letter, “**Minor Variations**” shall mean any modifications that do not result in a material deviation to the approved TI Construction Drawings and which are reasonably required: (i) to comply with all applicable Legal Requirements and/or to obtain or to comply with any required permit (including the TI Permit); (ii) to comply with any request by Tenant for modifications to Landlord’s Work; (iii) to comport with good design, engineering, and construction practices that are not

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material; or (iv) to make reasonable adjustments for field deviations or conditions encountered during the construction of Landlord's Work.

(d) **Selection of Materials.** Where more than one type of material or structure is indicated on the TI Construction Drawings approved by Landlord and Tenant, the option will be selected at Landlord's reasonable discretion. As to all building materials and equipment that Landlord is obligated to supply under this Work Letter, Landlord shall select the manufacturer thereof in its reasonable discretion.

(e) **Delivery of the Premises.** When Landlord's Work is Substantially Complete, subject to the remaining terms and provisions of this Section 3(e), Tenant shall accept the Premises. Tenant's taking possession and acceptance of the Premises shall not constitute a waiver of: (i) any warranty with respect to workmanship (including installation of equipment) or material (exclusive of equipment provided directly by manufacturers), (ii) any non-compliance of Landlord's Work with applicable Legal Requirements, or (iii) any claim that Landlord's Work was not completed substantially in accordance with the TI Construction Drawings (subject to Minor Variations and such other changes as are permitted hereunder) (collectively, a "**Construction Defect**"). Tenant shall have one year after Substantial Completion within which to notify Landlord of any such Construction Defect discovered by Tenant, and Landlord shall use reasonable efforts to remedy or cause the responsible contractor to remedy any such Construction Defect within 30 days thereafter, at no expense to Tenant. Notwithstanding the foregoing, Landlord shall not be in default under the Lease if the applicable contractor, despite Landlord's reasonable efforts, fails to remedy such Construction Defect within such 30-day period. If the contractor fails to remedy such Construction Defect within a reasonable time, Landlord shall use reasonable efforts to remedy the Construction Defect within a reasonable period.

Tenant shall be entitled to receive the benefit of all construction warranties and manufacturer's equipment warranties relating to equipment installed in the Premises. If requested by Tenant, Landlord shall attempt to obtain extended warranties from manufacturers and suppliers of such equipment, but the cost of any such extended warranties shall be borne solely out of the TI Fund. Landlord shall promptly undertake and complete, or cause to be completed, all punch list items.

(f) **Commencement Date Delay.** Except as otherwise provided in the Lease, Delivery of the Premises shall occur when Landlord's Work has been Substantially Completed, except to the extent that completion of Landlord's Work shall have been actually delayed by any one or more of the following causes ("**Tenant Delay**"):

(i) Tenant's Representative was not available within the time period set forth in this Work Letter (or, if no time period is set forth in this Work Letter, then within 2 business days) to give or receive any Communication or to take any other action required to be taken by Tenant hereunder;

(ii) Tenant's request for Change Requests (as defined in Section 4(a) below) whether or not any such Change Requests are actually performed;

(iii) Construction of any Change Requests;

(iv) Tenant's request for materials, finishes or installations requiring unusually long lead times, provided that promptly after Landlord learns of such long lead times, Landlord informs Tenant that the requested items will require unusually long lead times;

(v) Tenant's delay in reviewing, revising or approving plans and specifications beyond the periods set forth herein;

(vi) Tenant's delay in providing information critical to the normal progression of the Project. Tenant shall provide such information as soon as reasonably possible, but in no event longer than one week after receipt of any request for such information from Landlord;

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(vii) Tenant's delay in making payments to Landlord for Excess TI Costs (as defined in Section 5(d) below); or

(viii) Any other act or omission by Tenant or any Tenant Party (as defined in the Lease), or persons employed by any of such persons that continues for more than 1 business day after Landlord's written notice to Tenant thereof.

If Delivery is delayed for any of the foregoing reasons, then Landlord shall cause the TI Architect to certify the date on which the Tenant Improvements would have been Substantially Completed but for such Tenant Delay and such certified date shall be the date of Delivery.

4. **Changes.** Any changes requested by Tenant to the Tenant Improvements or the Base Building Improvements ("**Changes**"), shall be requested and instituted in accordance with the provisions of this Section 4. and shall be subject to the written approval of Landlord.

(a) **Tenant's Request For Changes.** If Tenant shall request Changes to the Tenant Improvements, Tenant shall request such Changes by notifying Landlord in writing in substantially the same form as the AIA standard change order form (a "**Change Request**"), which Change Request shall detail the nature and extent of any such Change. Such Change Request must be signed by Tenant's Representative. Landlord shall, before proceeding with any Change, use commercially reasonable efforts to respond to Tenant as soon as is reasonably possible with an estimate of: (i) the time it will take, and

(ii) the architectural and engineering fees and costs that will be incurred, to analyze such Change Request (which costs shall be paid from the TI Fund to the extent actually incurred, whether or not such change is implemented). Landlord shall thereafter submit to Tenant in writing, within 5 business days of receipt of the Change Request (or such longer period of time as is reasonably required depending on the extent of the Change Request), an analysis of the additional cost or savings involved, including, without limitation, architectural and engineering costs and the period of time, if any, that the Change will extend the date on which Landlord's Work in the Phase 1 Premises or the Phase 2 Premises, as applicable, will be Substantially Complete. Any such delay in the completion of Landlord's Work caused by a Change, including any suspension of Landlord's Work while any such Change is being evaluated and/or designed, shall be Tenant Delay.

(b) **Implementation of Changes.** If Tenant approves in writing the cost or savings and the estimated extension in the time for completion of Landlord's Work, if any, Landlord shall cause the approved Change to be instituted. Notwithstanding any approval or disapproval by Tenant of any estimate of the delay caused by such proposed Change, the TI Architect's determination of the amount of Tenant Delay in connection with such Change shall be final and binding on Landlord and Tenant.

(c) **Implementation of Changes for Base Building Improvements.** If Tenant shall request Changes to the Base Building Improvements with respect to the Premises, Tenant shall request such Changes by delivery of a Change Request to Landlord, which Change Request shall detail the nature and extent of any such Change. If Landlord approves any Change to the Base Building Improvements, Landlord shall cause the Change to be instituted; provided, however, Tenant shall be responsible for the cost of such approved Changes and the TI Allowance shall be reduced by an amount equal to the cost of such approved Changes (each, a "**Base Building Improvements Change Cost**"). Landlord shall provide Tenant with the amount of such Base Building Improvements Change Costs together with reasonable back up information to support the applicable Base Building Improvements Change Costs with respect to any Change to the Base Building Improvements requested by Tenant and an estimate of any Tenant Delay that will result from such Change to the Base Building Improvements. Tenant shall have the opportunity to withdraw a requested Change to the Base Building Improvements within 5 business days following Tenant's receipt of Landlord's determination of the Base Building Improvements Change Cost

and estimate of Tenant Delay. Notwithstanding any approval or disapproval by Tenant of any estimate of the delay caused by such proposed Change to the Base Building Improvements, the architect's determination of the amount of Tenant Delay in connection with such Change to the Base Building

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Improvements shall be final and binding on Landlord and Tenant.

5. **Costs.**

(a) **Budget For Tenant Improvements.** Landlord shall submit the approved TI Construction Drawings to the General Contractor to obtain a proposed contract price for the design and construction of the Tenant Improvements (the “**Proposed Budget**”). General Contractor shall identify any items or components of the Tenant Improvements which General Contractor anticipates will be long lead items. Concurrent with the delivery of the Proposed Budget, the General Contractor shall prepare and deliver a detailed breakdown of the Proposed Budget, which breakdown shall include (i) the pricing for applicable line item components of the Tenant Improvements; (ii) Contractor’s percentage mark-up for overhead and profit (including charges for general conditions), and (iii) and the bids received from major trade subcontractors. Within 3 business days after the delivery of the Proposed Budget (including the detailed cost breakdown), Tenant may elect, by delivering notice (the “**Value Engineering Notice**”) to Landlord, the Architect and the General Contractor, to request that the Architect revise the TI Construction Drawings to reduce the cost of constructing the Tenant Improvements. If Tenant elects to submit a Value Engineering Notice, then the Architect shall revise the TI Construction Drawings and resubmit the revised TI Construction Drawings to Landlord and Tenant for review and approval in accordance with the procedures set forth in Section 2(c) above. After approval by Landlord and Tenant, the revised TI Construction Drawings shall be submitted to General Contractor to obtain an updated Proposed Budget. Landlord and Tenant shall work in good faith and expeditiously to resolve any and all disputes with respect to the Proposed Budget so as to cause the budget for the to be approved to occur by not later than the applicable dates set forth in the construction schedule. Without limiting the foregoing, Tenant shall respond to the Proposed Budget within 5 business days after receipt thereof, and shall not unreasonably withhold, condition or delay its approval of said Proposed Budget. The Proposed Budget, as prepared and submitted by Landlord and after approval thereof by Tenant, shall be considered to be the “**Approved Budget**”. The Approved Budget shall include a payment to Landlord of administrative rent (“**Administrative Rent**”) equal to 3% of the TI Costs for monitoring and inspecting the construction of the Tenant Improvements and Changes, which sum shall be payable from the TI Fund (as defined in Section 5(d)).

(b) **TI Allowance.** Landlord shall provide to Tenant a tenant improvement allowance (collectively, the “**TI Allowance**”) as follows:

1. a “**Tenant Improvement Allowance**” in the maximum amount of \$300.00 per rentable square foot in the Premises, which is included in the Base Rent set forth in the Lease; and
2. an “**Additional Tenant Improvement Allowance**” in the maximum amount of \$100.00 per rentable square foot in the Premises, which shall, to the extent used, result in TI Rent as set forth in Section 4(b) of the Lease.

Landlord and Tenant hereby acknowledge and agree that Tenant has agreed to use and apply not less than 50% of the Additional Tenant Improvement Allowance toward TI Costs. Following the disbursement of the full amount of the Tenant Improvement Allowance, Tenant shall notify Landlord if Tenant has elected to use any additional portion of the Additional Tenant Improvement Allowance Tenant. Such election shall be final and binding on Tenant, and may not thereafter be modified without Landlord’s consent, which may be granted or withheld in Landlord’s sole and absolute subjective discretion. The TI Allowance shall be disbursed in accordance with this Work Letter.

Tenant shall have no right to the use or benefit (including any reduction to or payment of Base Rent) of any portion of the TI Allowance not required for the construction of (i) the Tenant Improvements

described in the TI Construction Drawings approved pursuant to Section 2(d) or (ii) any Changes pursuant to Section 4.

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In addition to the TI Allowance, Landlord shall pay the TI Architect up to \$0.12 per rentable square foot of the Premises for the preparation of test fit drawings for the Premises.

(c) **Costs Includable in TI Fund.** The TI Fund shall be used solely for the payment of hard and soft costs incurred for the design, permitting and construction of the Tenant Improvements including, without limitation, architectural, engineering and project management fees, the cost of electrical power and other utilities used in connection with the construction of the Tenant Improvements, the cost of preparing the Space Plans and the TI Construction Drawings, all costs set forth in the Budget, including Landlord's Administrative Rent, Landlord's out-of-pocket expenses, the cost of Tenant's Project Manager (not to exceed 3% of the total cost of the Tenant Improvements) and the cost of Changes. (collectively, "**TI Costs**"). Except as otherwise provided in the immediately following sentence, the TI Fund shall not be used to purchase any furniture, personal property or other non-Building system materials or equipment, including, but not limited to, Tenant's voice or data cabling, non-ducted biological safety cabinets and other scientific equipment not incorporated into the Tenant Improvements (collectively, "**Tenant's FF&E and Cabling**"). Notwithstanding anything to the contrary contained herein, Tenant may apply the Additional Tenant Improvement Allowance toward the cost of Tenant's FF&E and Cabling reasonably approved by Landlord. Any such Tenant's FF&E and Cabling purchased all or in part with the Additional Tenant Improvement Allowance shall, subject to the terms of Section 12 of the Lease, become Landlord's property and remain in the Premises at the expiration or earlier termination of the Term.

(d) **Excess TI Costs.** Landlord shall have no obligation to bear any portion of the cost of any of the Tenant Improvements except to the extent of the TI Allowance. If at any time and from time-to-time, the remaining TI Costs under the Approved Budget exceed the remaining unexpended TI Allowance ("**Excess TI Costs**"), monthly disbursements of the TI Allowance shall be made on a "pari passu" basis in the proportion that the remaining TI Allowance bears to the outstanding TI Costs under the Approved Budget, and Tenant shall fund the balance of each such monthly draw. For purposes of any litigation instituted with regard to such amounts, those amounts required to be paid by Tenant will be deemed Rent under the Lease. The TI Allowance and Excess TI Costs are herein referred to as the "**TI Fund.**" Notwithstanding anything to the contrary set forth in this Section 5(d), Tenant shall be fully and solely liable for TI Costs and the cost of Minor Variations in excess of the Tenant Improvement Allowance and, if elected, the Additional Tenant Improvement Allowance.

**6. Tenant Access.**

(a) **Tenant's Access Rights.** Landlord hereby agrees to permit Tenant access, at Tenant's sole risk and expense, (i) to the Phase 1 Premises 30 days prior to the Commencement Date (and/or at such other times prior to such 30-day period as may be reasonably agreed upon by Landlord and Tenant) and to the Phase 2 Premises 30 days prior to the Phase 2 Commencement Date (and/or at such other times prior to such 30-day period as may be reasonably agreed upon by Landlord and Tenant) to perform any work ("**Tenant's Work**") required by Tenant other than Landlord's Work, provided that such Tenant's Work is coordinated with the TI Architect and the General Contractor, and complies with the Lease and all other reasonable restrictions and conditions Landlord may impose, and (ii) prior to the completion of Landlord's Work in the Phase 1 Premises or the Phase 2 Premises, as applicable, to inspect and observe work in process; all such access shall be during normal business hours or at such other times as are reasonably designated by Landlord. Notwithstanding the foregoing, Tenant shall have no right to enter onto the Premises or the Project unless and until Tenant shall deliver to Landlord evidence reasonably satisfactory to Landlord demonstrating that any insurance reasonably required by Landlord in connection with such pre-commencement access (including, but not limited to, any insurance that Landlord may require pursuant to the Lease) is in full force and effect. Any entry by Tenant shall comply with all established safety practices of Landlord's contractor and Landlord until completion of Landlord's Work and acceptance thereof by Tenant.

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(b) **No Interference.** Neither Tenant nor any Tenant Party (as defined in the Lease) shall interfere with the performance of Landlord's Work, nor with any inspections or issuance of final approvals by applicable Governmental Authorities, and upon any such interference, Landlord shall have the right to exclude Tenant and any Tenant Party from the Premises and the Project until Substantial Completion of Landlord's Work.

(c) **No Acceptance of Premises.** The fact that Tenant may, with Landlord's consent, enter into the Project prior to the date Landlord's Work is Substantially Complete for the purpose of performing Tenant's Work shall not be deemed an acceptance by Tenant of possession of the Premises, but in such event Tenant shall defend with counsel reasonably acceptable by Landlord, indemnify and hold Landlord harmless from and against any loss of or damage to Tenant's property, completed work, fixtures, equipment, materials or merchandise, and from liability for death of, or injury to, any person, caused by the act or omission of Tenant or any Tenant Party.

7. **Miscellaneous.**

(a) **Consents.** Whenever consent or approval of either party is required under this Work Letter, that party shall not unreasonably withhold, condition or delay such consent or approval, unless expressly set forth herein to the contrary.

(b) **Modification.** No modification, waiver or amendment of this Work Letter or of any of its conditions or provisions shall be binding upon Landlord or Tenant unless in writing signed by Landlord and Tenant.

(c) **No Default Funding.** In no event shall Landlord have any obligation to fund any portion of the TI Allowance or to perform any Landlord's Work during any period that Tenant is in Default under the Lease.

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**Schedule 1**  
**Landlord/Tenant Matrix**



## TENANT MATRIX

## CHARLES PARK

ONE CHARLES PARK  
CAMBRIDGE, MA  
5192.00

09.30.2021

ARCHITECTURE | PLANNING  
INTERIOR DESIGN | VDC  
BRANDED ENVIRONMENTS

BOSTON  
200 HIGH ST, FLOOR 2  
BOSTON, MA 02110

NEW YORK  
54 W 21ST ST, SUITE 804  
NEW YORK, NY 10010

SGA-ARCH.COM  
857.300.2630

DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>GENERAL</b>		
Building Core & Shell shall be LEED certified by the USGBC at not less than GOLD	X	
<b>SITework</b>		
Perimeter sidewalks, street curbs, miscellaneous site furnishings and landscaping	X	
Telephone service to main demarcation room from local exchange carrier	X	
Domestic sanitary sewer connection to street	X	
Lab waste sewer connection	X	
Roof storm drainage	X	
Electrical service to main switch room	X	
Gas service	X	
Domestic water service to Building	X	
Fire protection water service to Building	X	
<b>LANDSCAPING</b>		
Hardscape plans shall include walkways, driveways, curbing, exterior lighting, and non-Tenant signage. Design and site improvements materials shall be of Class A Building quality.	X	
<b>STRUCTURE</b>		
Rogers: Typical lab 100 psf, Mechanical level 150 psf Live Load, 50 psf 4" housekeeping pad, 100 psf equipment	X	
Charles: Typical lab 100 psf, Mechanical level 150 psf Live Load, 50 psf housekeeping pad, 100 psf equipment	X	
Structural enhancements for specific Tenant load requirements		X
Structural reinforcing meets vibration criterion of 8,000 micro inches per second at 50 steps per minute.	X	



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NEW YORK, NY 10010SGA-ARCH.COM  
857.300.2610

DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>STRUCTURE</b>		
Typical Floor to Floor height framing as follows: Floor 1 = 17'-1", Floors= 2-5 13'-1", Floor 6 =13'-2"	X	
Column bay spacing : Rogers: 30'-0"X 30'-0", Charles: 30'X35'-0", 30'X29'-9"	X	
Structural framing dunnage above roof for Base Building equipment	X	
Structural framing dunnage above roof for Tenant equipment subject to Landlord review and approval		X
Framed openings for Base Building utility risers	X	
Framed openings for Tenant utility risers in addition to Base Building within pre-allocated Base Building areas subject to Landlord review and approval	X	
Miscellaneous metals items and/or concrete pads for Base Building equipment	X	
Miscellaneous metals items and/or concrete pads for Tenant equipment		X
<b>ROOFING</b>		
TPO membrane roofing	X	
Roofing penetrations for Base Building equipment/systems	X	
Roofing penetrations for Tenant equipment/systems, installed by Base Building roofing subcontractor		X
Walkway pads to Base Building equipment	X	
Walkway pads to Tenant equipment		X
Roofing alterations due to Tenant changes within Building penthouse, installed by Base Building roofing subcontractor		X



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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>EXTERIOR</b>		
Building exterior envelope	X	
Base Building entrances	X	
Building-mounted signage and/or ground-mounted exterior signage for Tenant identification, subject to City Zoning and Permitting		X
Loading dock overhead door (s)	X	
Penthouse enclosure for Base Building rooftop equipment	X	
Penthouse enclosure for Tenant rooftop equipment (within base building penthouse)	X	
<b>COMMON AREAS</b>		
Accessible main entrance. Entrance vestibules will include integrated security hardware.	X	
Egress corridors on multi-tenant floors	X	
First floor finished lobby consistent with a Class A Cambridge building.	X	
Core area toilet rooms. Floors and base shall be thin set ceramic tile. Full height ceramic tile shall be provided on wet walls. All other wall surfaces shall be painted drywall. Lavatory counters shall be solid surface with integral sinks, and continuous mirror above lavatory counters. Metal toilet enclosures shall be floor mounted, steel panel construction with a painted finish. Toilet room accessories shall be similar or equal to those manufactured by ASI & Bobrick Company, all in accordance with handicapped accessibility regulations.	X	
Shower/Locker Rooms. Floors and base shall be thin set ceramic tile. Full height ceramic tile shall be provided on wet walls. All other wall surfaces shall be painted drywall. Lavatory counters shall be solid surface with integral sinks, and continuous mirror above lavatory counters.	X	
Walls in toilet rooms, stairways, and Base Building utility rooms shall have a final paint finish	X	
Painted metal railings in all stairways	X	
Interior signage for all Base Building rooms (as required by Code)	X	





## TENANT MATRIX

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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>COMMON AREAS</b>		
Janitor's closets in core areas.	X	
Electrical closets in core areas. Electrical closets can be used for Tenant-provided electrical equipment, subject to coordination with Base Building equipment, and conformance to all Code requirements.	X	
Stacked tel/data riser closet for connectivity between demarcation room and tenant's remote IDF.	X	
Demarcation room	X	
Loading dock area with dock levelers, 48" high at raised position	X	
Doors, frames, and hardware at common areas	X	
Parking control equipment in garage	X	
<b>ELEVATORS</b>		
Charles-2 Passenger elevators with 3,500 lb. capacity, 200 FPM. Each serves main lobby Level 1 through Level 6, 1 Service elevator, 5000 lb. capacity, 54", 150 FPM	X	
Rogers- 6 passenger elevators, 1 Service elevator at with 4,500 lb. capacity, 200 FPM, 4'-0" wide door opening. Serves main lobby Level 1 through mechanical penthouse.	X	
<b>WINDOW TREATMENT</b>		
New window treatments specification and installation detail standard by SGA detail for Cove at Window for manual or motorized shade.		X
<b>TENANT AREAS</b>		
Drywall and finishes at inside face of exterior fire rated walls	X	
Drywall and finishes at inside face of exterior non fire-rated walls and column enclosures		X
Finishes at inside face at Tenant side of core partitions		X
Additional toilet rooms within Tenant Premises		X

**Work Letter – Tenant Build**

**One Charles Park – Suite 501/Omega Therapeutics - Page 5**



TENANT MATRIX

CHARLES PARK

ONE CHARLES PARK  
CAMBRIDGE, MA  
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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>TENANT AREAS (Continued)</b>		
Tenant Premises HVAC and Plumbing Rooms		X
Electrical closets within Tenant Premises		X
Tel./data rooms for interconnection with Tenant tel./data		X
Tenant kitchen areas		X
Drywall and finishes at inside face of exterior fire rated walls	X	
Drywall and finishes at inside face of exterior non fire-rated walls and column enclosures		X
Tel./data rooms for interconnection with Tenant tel./data		X
Tenant kitchen areas		X
Modifications to core areas to accommodate Tenant requirements		X
Partitions, ceilings, flooring, painting, finishes, doors, frames, hardware, millwork, casework, and buildout at Tenant spaces		X
Fixed or movable casework		X
Laboratory equipment including, but not limited to, biosafety cabinets, autoclaves, glasswashers, bioreactors		X
Chemical fume hoods, bench fume hood, lab casework		X
Shaft enclosures for Base Building systems' risers	X	
Shaft enclosures for Tenant risers outside of the allocated space in the main vertical Base Building shafts		X
All interior signage for Tenant Premises		X
Sound attenuation upgrades for Tenant Premises to comply with Tenant acoustical criteria and design of Tenant Areas		X



## TENANT MATRIX

CHARLES PARK

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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>FIRE PROTECTION</b>		
Fire service entrance including fire department connection, alarm valve, and back flow protection	X	
Base Building area distribution piping and up-turned sprinkler heads	X	
Stair distribution piping and sprinkler heads	X	
Primary distribution and sprinkler heads adequate to support ordinary hazard (with upturned heads).	X	
Revisions/modifications to sprinkler mains, run outs, drop heads, and related equipment within Tenant Premises.		X
Modification of sprinkler piping and head locations to suit Tenant layout and hazard index		X
Specialized extinguishing systems		X
Preaction dry-pipe systems (if required) within Tenant Premises		X
Fire extinguisher cabinets within Base Building areas	X	
Fire extinguisher cabinets within Tenant Premises		X
Standpipes, distribution and hose connections within egress stairs, and lobby	X	
Additional hose connections within Tenant Premises, including distribution piping		X
<b>PLUMBING</b>		
Domestic water distribution within Tenant Premises		X
Domestic water service with backflow prevention and Base Building risers	X	
Base Building restroom plumbing fixtures compliant with accessibility requirements	X	
Tenant restroom plumbing fixtures compliant with accessibility requirements (in addition to those provided by the Base Building)		X
Storm drainage system	X	
Sanitary waste and vent service for Base Building areas	X	
Sanitary waste and vent service for Tenant Premises		X



## TENANT MATRIX

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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
Hot water generation for Base Building restrooms	X	
Non-potable water risers for lab use including water booster system and reduced pressure backflow preventer	X	
Non-potable water distribution within Tenant Premises		X
Two stage active pH neutralization system	X	
Lab waste and vent pipe risers	X	
Lab waste and vent pipe distribution serving Tenant Premises including sampling trap at connection to house risers.		X
Non-potable hot water generation for Tenant use		X
Compressed air generation equipment		X
Compressed air piping risers and distribution within tenant premises		X
Laboratory vacuum generation equipment		X
Lab vacuum risers and distribution within tenant premises		X
Tepid hot water generation and riser piping for emergency eyewash/showers serving based building fixtures and capped for future tenant extension.	X	
Tepid water pipe distribution and emergency fixtures within tenant premises.		X
Purified water generation equipment		X
Purified water pipe risers and distribution within tenant premises		X
Manifolds, piping, bulk tanks, and other requirements for specialty gases.		X
<b>NATURAL GAS</b>		
Natural gas service to Building	X	
Natural gas service to Base Building boilers	X	
Natural gas service, pressure regulator and meter for Tenant equipment		X
Natural gas piping from Tenant meter to Tenant Premises or Tenant equipment area		X
Natural gas pipe distribution within Tenant Premises		X



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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
Natural gas pressure regulator vent pipe riser from tenant meter location through roof		X
<b>HEATING, VENTILATION, AIR CONDITIONING</b>		
Cooling towers, supporting condenser water pumps and piping	X	
Stair pressurization if required by code	X	
Main electric room ventilation system	X	
Central gas fired boiler plant	X	
Hot water pipe risers	X	
Chilled water pipe risers	X	
Condenser water pipe risers	X	
Hot water pipe distribution within Tenant Premises		X
Chilled water pipe distribution within Tenant Premises		X
Condenser water pipe distribution within Tenant Premises		X
Reheat coils within Tenant Premises		X
Reheat coils within Base Building areas	X	
Building Management System (BMS) for Base Building	X	
BMS (compatible with Landlord's system) within Tenant's Premises monitoring Tenant infrastructure.		X
Supply air duct distribution, VAV terminals or fan coils, equipment connections, insulation, air terminals, dampers, hangers, etc. within Tenant Premises		X
Supply air duct distribution, VAV terminals or fan coils, equipment connections, insulation, air terminals, dampers, hangers, etc. within Base Building areas.	X	
Restroom exhaust for Base Building area restrooms	X	
Restroom exhaust for new restrooms built within Tenant Premises		X
Electric room ventilation system for Base Building electrical closets with base building heat generating equipment	X	
Electric room ventilation system for electrical closets within Tenant Premises and tenant heat gains in base building closets		X



## TENANT MATRIX

## CHARLES PARK

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NEW YORK  
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857.300.2610

DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>HEATING, VENTILATION, AIR CONDITIONING (Continued)</b>		
Sound attenuation for Base Building equipment to comply with Zoning Ordinance	X	
Sound attenuation for Tenant equipment to comply with Zoning Ordinance		X
Additional/ dedicated cooling equipment for Tenant requirements		X
Hot water and chilled water risers for future tenant office HVAC distribution systems	X	
Fan coils, heat pumps, chilled beams and associated distribution and controls to support office HVAC.		X
Heating Capacity (Boilers+ Heat Recovery) Office: 30 BTU/SF Lab: 150 BTU/SF	X	
Chiller Capacity – Office: 350 SF / Ton Lab: 100 SF/Ton	X	
Supply air handling units with MERV 15 filtration, heat recovery coils, chilled water cooling coils, and multiple supply fans sized for approximately 1.75 CFM/SF for lab areas and 0.25 CFM/SF for office areas using a 60/40 Lab/office ratio.	X	
Exhaust air handling units with MERV 8 filtration, heat recovery coils and multiple exhaust fans sized for approximately 1.75 CFM/SF for lab areas and 0.25 CFM/SF for office areas using a 60/40 Lab/office ratio	X	
Supply air duct risers with takeoff at each floor including fire/smoke damper and volume damper.	X	
Supply air distribution from duct shaft takeoff to tenant supply air requirements in tenant premises		X
Exhaust air duct risers with sub-duct takeoff at each floor including volume damper	X	
Exhaust air distribution from duct shaft takeoff to tenant exhaust air requirements in tenant premises		X
Exhaust systems including ductwork, risers, roof mounted fans, etc serving specialized tenant requirements (hazardous exhaust, vivarium systems, high static requirements, etc)		X
<b>ELECTRICAL</b>		
Diesel life safety generator with sound attenuation to comply with local zoning ordinance	X	
Natural Gas Tenant Optional Standby Generator with sound attenuation to comply with local zoning ordinance	X	
Rogers 480/277V bus riser in electrical closets for Tenant connection, Charles 480/277V distribution panels.	X	



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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
Bus plug, check meter, and disconnect for bus tie in at Rogers	X	
Electric Check meter on tenant distribution panels at Charles to lights, plugs, HVAC and general power on floor, compatible with and tied back to Landlord BMS Metering System	X	
Standby power distribution within Tenant Premises		X
Lighting and power distribution for Base Building areas	X	
Lighting and power distribution for Tenant Premises		X
Life safety emergency lighting/signage including panels and circuit breakers for Base Building areas	X	
Life safety emergency lighting/signage for Tenant Premises		X
Tenant panels, transformers, etc. for tenant areas		X
Panels, transformers, etc serving base building areas	X	
Allocation of building power for Tenant use (w/USF): <ul style="list-style-type: none"> <li>Office Lighting: 1.5w / SF</li> <li>Office Power: 5w / SF</li> <li>Office Mech: 1.5w / SF</li> <li>Lab Lighting: 1.5w / SF</li> <li>Lab Power: 12w / SF</li> <li>Lab Mech: 1.5w / SF</li> </ul>	X	
Allocation of building emergency power for Tenant use (w/SF): <ul style="list-style-type: none"> <li>Tenant Life Safety: 0.25w / SF</li> </ul>	X	
Allocation of building optional standby power for Tenant use (w/Lab USF based on 60/40 lab/office ratio): <ul style="list-style-type: none"> <li>Tenant Standby Power: 5w / SF</li> </ul>	X	
Lighting protection system for base building and all base building equipment.	X	
Extension of base building lightning protection system for new tenant equipment.		X
<b>FIRE ALARM</b>		
Base Building fire alarm system with devices within Base Building areas	X	
Fire alarm sub panels and devices for Tenant Premises with integration into Base Building system		X
Alteration to fire alarm system to facilitate Tenant program		X



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DESCRIPTION (Lab/Office)	RESPONSIBILITY	
	Landlord	Tenant
<b>TELEPHONE/DATA</b>		
Underground local exchange carrier service to primary demarcation room	X	
Service from primary demarcation room to secondary demarcation room	X	
Tel/data riser closet	X	
Tenant tel./data rooms		X
Pathways from demarcation room directly into Tenant tel./data rooms		X
Tel./Data cabling (demarcation rms. to intermediate distribution frame rms.)		X
Tel./Data cabling from demarcation room and/ or intermediate distribution frame rooms to Tenant tel./data room		X
Fiber optic service for Tenant use		X
Tel./data infrastructure including, but not limited to, servers, computers, phone systems, switches, routers, MUX panels, equipment racks, ladder racks, etc.		X
Provisioning of circuits and service from service providers		X
Audio visual systems and support		X
Station cabling from Tenant tel./data room to all Tenant locations, within the suite and exterior to the suite, if needed		X
<b>SECURITY</b>		
Card access at Building entries and Elevators	X	
Card access into or within Tenant Premises on separate Tenant installed and managed system		X
Video camera coverage of Tenant Premises on separate Tenant installed and managed system		X

CHARLES PARK: LANDLORD / TENANT MATRIX | 11

For the avoidance of doubt, it is understood that all wattages, pressures, volumes and other capacities referenced or specified in this Schedule 1 are included only to specify capacities for which applicable systems are designed.





EXHIBIT D TO LEASE

**ACKNOWLEDGMENT OF COMMENCEMENT DATE**

This **ACKNOWLEDGMENT OF COMMENCEMENT DATE** is made this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_, between **ARE-MA REGION NO. 94, LLC**, a Delaware limited liability company ("**Landlord**"), and **OMEGA THERAPEUTICS, INC.**, a Delaware corporation ("**Tenant**"), and is attached to and made a part of the Lease dated \_\_\_\_\_, \_\_\_\_\_ (the "**Lease**"), by and between Landlord and Tenant. Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

Landlord and Tenant hereby acknowledge and agree, for all purposes of the Lease, that the Commencement Date is \_\_\_\_\_, \_\_\_\_\_, the Phase 2 Commencement Date is \_\_\_\_\_, \_\_\_\_\_, and the termination date of the Base Term of the Lease shall be midnight on \_\_\_\_\_, \_\_\_\_\_. In case of a conflict between the terms of the Lease and the terms of this Acknowledgment of Commencement Date, this Acknowledgment of Commencement Date shall control for all purposes.

IN WITNESS WHEREOF, Landlord and Tenant have executed this **ACKNOWLEDGMENT OF COMMENCEMENT DATE** to be effective on the date first above written.

**TENANT:**

**OMEGA THERAPEUTICS, INC.**,  
a Delaware corporation

By: \_\_\_\_\_  
Its: \_\_\_\_\_

[ ] I hereby certify that the signature, name, and title above are my signature, name and title.

**LANDLORD:**

**ARE-MA REGION NO. 94, LLC**,  
a Delaware limited liability company

By: **ALEXANDRIA REAL ESTATE EQUITIES, L.P.**,  
a Delaware limited partnership,  
managing member

By: **ARE-QRS CORP.**,  
a Maryland corporation  
general partner

By: \_\_\_\_\_  
Print name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**Rules and Regulations**

**One Charles Park – Suite 501/Omega Therapeutics - Page 1**

**EXHIBIT E TO LEASE**

**Rules and Regulations**

1. The sidewalk, entries, and driveways of the Project shall not be obstructed by Tenant, or any Tenant Party, or used by them for any purpose other than ingress and egress to and from the Premises.
  2. Tenant shall not place any objects, including antennas, outdoor furniture, etc., in the parking areas, landscaped areas or other areas outside of its Premises, or on the roof of the Project.
  3. Except for animals assisting the disabled, no animals shall be allowed in the offices, halls, or corridors in the Project.
  4. Tenant shall not disturb the occupants of the Project or adjoining buildings by the use of any radio or musical instrument or by the making of loud or improper noises.
  5. If Tenant desires telegraphic, telephonic or other electric connections in the Premises, Landlord or its agent will direct the electrician as to where and how the wires may be introduced; and, without such direction, no boring or cutting of wires will be permitted. Any such installation or connection shall be made at Tenant's expense.
  6. Tenant shall not install or operate any steam or gas engine or boiler, or other mechanical apparatus in the Premises, except as specifically approved in the Lease. The use of oil, gas or inflammable liquids for heating, lighting or any other purpose is expressly prohibited. Explosives or other articles deemed extra hazardous shall not be brought into the Project.
  7. Parking any type of recreational vehicles is specifically prohibited on or about the Project. Except for the overnight parking of operative vehicles, no vehicle of any type shall be stored in the parking areas at any time. In the event that a vehicle is disabled, it shall be removed within 48 hours. There shall be no "For Sale" or other advertising signs on or about any parked vehicle. All vehicles shall be parked in the designated parking areas in conformity with all signs and other markings. All parking will be open parking, and no reserved parking, numbering or lettering of individual spaces will be permitted except as otherwise set forth in the Lease.
  8. Tenant shall maintain the Premises free from rodents, insects and other pests.
  9. Landlord reserves the right to exclude or expel from the Project any person who, in the judgment of Landlord, is intoxicated or under the influence of liquor or drugs or who shall in any manner do any act in violation of the Rules and Regulations of the Project.
  10. Tenant shall not cause any unnecessary labor by reason of Tenant's carelessness or indifference in the preservation of good order and cleanliness. Landlord shall not be responsible to Tenant for any loss of property on the Premises, however occurring, or for any damage done to the effects of Tenant by the janitors or any other employee or person.
  11. Tenant shall give Landlord prompt notice of any defects in the water, lawn sprinkler, sewage, gas pipes, electrical lights and fixtures, heating apparatus, or any other service equipment affecting the Premises.
  12. Tenant shall not permit storage outside the Premises, including without limitation, outside storage of trucks and other vehicles, or dumping of waste or refuse or permit any harmful materials to be placed in any drainage system or sanitary system in or about the Premises.
  13. All moveable trash receptacles provided by the trash disposal firm for the Premises must be
-

**Rules and Regulations**

**One Charles Park – Suite 501/Omega Therapeutics - Page 2**

kept in the trash enclosure areas, if any, provided for that purpose.

14. No auction, public or private, will be permitted on the Premises or the Project.
  15. No awnings shall be placed over the windows in the Premises except with the prior written consent of Landlord.
  16. The Premises shall not be used for lodging, sleeping or cooking (except that Tenant may use microwave ovens, toasters and coffee makers in the Premises for the benefit of Tenant's employees and contractors in an area designated for such items, but only if the use thereof is at all times supervised by the individual using the same) or for any immoral or illegal purposes or for any purpose other than that specified in the Lease. No gaming devices shall be operated in the Premises.
  17. Tenant shall ascertain from Landlord the maximum amount of electrical current which can safely be used in the Premises, taking into account the capacity of the electrical wiring in the Project and the Premises and the needs of other tenants, and shall not use more than such safe capacity. Landlord's consent to the installation of electric equipment shall not relieve Tenant from the obligation not to use more electricity than such safe capacity.
  18. Tenant assumes full responsibility for protecting the Premises from theft, robbery and pilferage.
  19. Tenant shall not install or operate on the Premises any machinery or mechanical devices of a nature not directly related to Tenant's ordinary use of the Premises and shall keep all such machinery free of vibration, noise and air waves which may be transmitted beyond the Premises.
  20. Tenant shall cause any vendors and other service providers hired by Tenant to perform services at the Premises or the Project to maintain in effect workers' compensation insurance as required by Legal Requirements and commercial general liability insurance with coverage amounts reasonably acceptable to Landlord. Tenant shall cause such vendors and service providers to name Landlord and Alexandria Real Estate Equities, Inc. as additional insureds under such policies and shall provide Landlord with certificates of insurance evidencing the required coverages (and showing Landlord and Alexandria Real Estate Equities, Inc. as additional insureds under such policies) prior to the applicable vendor or service provider providing any services to Tenant at the Project.
  21. Neither Tenant nor any of the Tenant Parties shall have the right to photograph, videotape, film, digitally record or by any other means record, transmit and/or distribute any images, pictures or videos of all or any portion of the Premises or the Project that could identify the Project or the name of the Project, or that identify Landlord or any other tenants or any affiliates of Landlord or any other tenants. The foregoing is not meant to prohibit individual employees from taking and disseminating photos of themselves or other people within the Premises or at the Project so long as neither the Building nor any proprietary information, equipment or improvements of Landlord are included within such photos.
  22. Tenant shall regularly review the guidelines published by the Centers for Disease Control (CDC) and any state and/or local Governmental Authorities, and will implement the practices and procedures suggested thereby, as well as industry standard best practices, to prevent the spread of Infectious Conditions, including, without limitation, COVID-19.
  23. Landlord shall have the right to (a) require tenants to implement and enforce reasonable screening and tracking protocols intended to identify and track the activity at the Project of employees, agents, contractors and visitors seeking access to or accessing the Premises and or the Project exhibiting flu-like symptoms or symptoms consistent with those associated with any currently known or unknown Infectious Conditions including, without limitation, COVID-19 (collectively, "**Symptoms**"), (b) require tenant employees, agents, contractors and visitors to comply with reasonable screening and tracking protocols implemented by Landlord, Landlord's property manager and/or any operator of Project Amenities, intended
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**Rules and Regulations**

**One Charles Park – Suite 501/Omega Therapeutics - Page 3**

to identify and track the activity at the Project of individuals seeking access to or accessing the Premises or the Project (including the Project Amenities) exhibiting Symptoms, (c) require tenants to implement and enforce protocols to prohibit individuals exhibiting Symptoms, from accessing the Premises and/or the Project, (d) require tenants to immediately report to Landlord incidences of (i) tenant employees, agents, contractors and visitors accessing the Premises or any portion of the Project while exhibiting Symptoms, and/or (ii) tenant employees, agents, contractors and visitors known to have accessed the Premises or the Project being diagnosed with an Infectious Condition including, without limitation, COVID-19.

24. Landlord may exclude or expel from the Project any person that has Symptoms associated with any currently known or unknown Infectious Condition including, without limitation, COVID- 19.

25. Notwithstanding anything to the contrary contained herein, if, at any time during the Term, Landlord becomes aware that any Tenant Party exhibiting Symptoms (that is subsequently diagnosed with an Infectious Condition) and/or a Tenant Party diagnosed with an Infectious Condition had access to the Premises or any portion of the Project (including, without limitation, the Project Amenities), Tenant shall be responsible for any deep cleaning reasonably required within the Premises and any reasonable costs incurred by Landlord to perform additional or deep cleaning of the Common Areas of the Project or to take other measures deemed reasonably necessary or prudent by Landlord which are intended to limit the spread of such Infectious Condition due to such Tenant Party's presence at the Project.

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**EXHIBIT F TO LEASE TENANT'S**

**PERSONAL PROPERTY**

None.

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EXHIBIT G TO LEASE

**FORM OF SHARED SPACE CONSENT**

This Consent (this “**Consent**”) is made as of \_\_\_\_\_, 202\_\_, by and among **ARE-MA REGION NO. 94, LLC**, a Delaware limited liability company, having an address of 26 North Euclid Avenue, Pasadena, California 91101 (“**Landlord**”), on the one hand, and **OMEGA THERAPEUTICS, INC.**, a Delaware corporation (“**Tenant**”), having an address of \_\_\_\_\_, and (“**Space Occupant**”), having an address of \_\_\_\_\_, having an address of \_\_\_\_\_, with reference to the following Recitals.

**RECITALS**

**A.** Landlord and Tenant have entered into that certain Lease Agreement dated November \_\_\_\_, 2021 (as the same may have been amended and may be in the future be amended, the “**Lease**”) wherein Tenant leases certain premises consisting of approximately 89,246 rentable square feet (the “**Premises**”) in a building known as One Charles Park, Cambridge, Massachusetts.

**B.** Tenant desires to permit Space Occupant to use and occupy a portion of the Premises (the “**Licensed Premises**”) more particularly described in and pursuant to the provisions of that certain License Agreement dated as of \_\_\_\_\_, 20\_\_ (the “**License**”), a copy of which is attached hereto as Exhibit A.

**C.** Tenant desires to obtain Landlord's consent to the License.

**NOW, THEREFORE**, in consideration of the foregoing and the agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord hereby consents to the license of the Licensed Premises to Space Occupant, such consent being subject to and upon the following terms and conditions to which Tenant and Space Occupant hereby agree:

1. All initially capitalized terms not otherwise defined in this Consent shall have the meanings set forth in the Lease unless the context clearly indicates otherwise.

2. This Consent shall not be effective and the License shall not be valid unless and until Landlord shall have received: (a) a fully executed copy of the License, (b) an executed counterpart of this Consent executed by Tenant and Space Occupant, and (c) an insurance certificate from Space Occupant, as insured, evidencing no less than the insurance requirements set forth in Section 17 of the Lease. Tenant and Space Occupant each represent and warrant to Landlord that the copy of the License attached hereto as Exhibit A is true, correct and complete.

3. Landlord neither approves nor disapproves the terms, conditions and agreements contained in the License, all of which shall be subordinate and at all times subject to: (a) all of the covenants, agreements, terms, provisions and conditions contained in the Lease, (b) superior ground leases, mortgages, deeds of trust, or any other hypothecation or security now existing or hereafter placed upon the real property of which the Premises are a part and to any and all advances secured thereby and to all renewals, modifications, consolidations, replacements and extensions thereof, and (c) all matters of record affecting the Premises and all laws, ordinances and regulations now or hereafter affecting the Premises.

4. Notwithstanding anything in the License to the contrary:

(a) Landlord and Space Occupant each hereby release the other, and waive their respective rights of recovery against the other for direct or consequential loss or damage arising out of or incident to the perils covered by property insurance carried by such party to the extent of such insurance and waive any right of subrogation which might otherwise exist in or accrue to any person on account thereof.

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(b) Tenant and Space Occupant agree to each of the terms and conditions of this Consent, and upon any conflict between the terms of the License and this Consent, the terms of this Consent shall control.

(c) If Landlord terminates the Lease as a result of a default by Tenant thereunder or the Lease terminates for any other reason, Landlord shall have no responsibility, liability or obligation to Space Occupant, and the License shall automatically terminate concurrently therewith.

5. Tenant hereby indemnifies and agrees to hold Landlord harmless from and against any loss or liability arising from any commissions or fees payable in connection with the License.

6. Space Occupant waive all rights of recovery against Landlord for direct or consequential loss or damage arising out of or incident to the perils covered by property insurance carried or required be carried by Landlord and waives any right of subrogation which might otherwise exist in or accrue to Space Occupant on account thereof.

7. Tenant and Space Occupant agree not to make any amendment to the License that would be contrary to the terms of the Lease or this Consent. Tenant and Space Occupant further agree that the License will not be modified or amended in any way without prior written notice to Landlord.

8. This Consent may not be changed orally, but only by an agreement in writing signed by Landlord and the party against whom enforcement of any change is sought.

9. This Consent may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Lease and all matters related thereto, with such electronic signatures having the same legal effect as original signatures. IN WITNESS WHEREOF, Landlord and Tenant have executed this Consent as of the day and year first above written.

10. This Consent and the legal relations between the parties hereto shall be governed by and construed and enforced in accordance with the internal laws of Commonwealth of Massachusetts, without regard to its principles of conflicts of law.

11. Tenant and Space Occupant are currently (a) in compliance with (and are required to at all times during the term of the License to remain) in compliance with the regulations of the Office of Foreign Assets Control (“**OFAC**”) of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the “**OFAC Rules**”), (b) not listed on, and shall not during the term of the License be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

[ Signatures on next page ]

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IN WITNESS WHEREOF, Landlord, Tenant and Space Occupant have caused their duly authorized representatives to execute this Consent as of the date first above written.

**LANDLORD:**

**ARE-MA REGION NO. 94, LLC,**  
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,  
a Delaware limited partnership,  
managing member

By: ARE-QRS CORP.,  
a Maryland corporation  
general partner

By: \_\_\_\_\_  
Print name: \_\_\_\_\_  
Title: \_\_\_\_\_

**TENANT:**

**OMEGA THERAPEUTICS, INC.,**  
a Delaware corporation

By: \_\_\_\_\_  
Its: \_\_\_\_\_

[ ] I hereby certify that the signature, name, and title above are my signature, name and title.

**SPACE OCCUPANT:**

\_\_\_\_\_, a  
\_\_\_\_\_

By: \_\_\_\_\_  
Its: \_\_\_\_\_

[ ] I hereby certify that the signature, name, and title above are my signature, name and title.



**AMENDMENT NO. 1 TO THE  
SHARED SPACE ARRANGEMENT**

This AMENDMENT NO. 1 TO THE SHARED SPACE ARRANGEMENT (the “**Amendment**”), is made effective as of January 31, 2022 (the “**Effective Date**”) by and between SENDA BIOSCIENCES, Inc., (formerly Kintai Therapeutics, Inc.) a Delaware corporation (“**Licensor**”), and OMEGA THERAPEUTICS, INC., a Delaware corporation (“**Licensee**”). All capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings set forth in the Agreement (as defined below).

**RECITALS**

**WHEREAS**, Licensee licenses the Shared Space from Licensor pursuant to that certain Shared Space Arrangement, dated July 13, 2020, by and between Licensor and Licensee (the “**Agreement**”).

**WHEREAS**, the Initial Term of the Agreement expires on July 31, 2022; and Section 3(a) of the Agreement provides Licensee with two (2) options to extend the Initial Term for twenty-four (24) months each by delivery of an Extension Notice.

**WHEREAS**, the parties desire to amend the Agreement to modify Section 3(a) of the Agreement to shorten the Extension Term to twelve (12) months and delete the right to exercise for a second Extension Term. Licensee desires to exercise the option and this Amendment shall constitute the Exercise Notice for purposes of the Agreement.

**NOW THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Licensor and Licensee hereby agree to the following:

**1.Term:** As of the Effective Date, Section 3(a) of the Agreement shall be deleted in its entirety and replaced as set forth below:

“(a) The term (“**Term**”) of this Shared Space Arrangement shall commence on August 1, 2020 (the “**Term Commencement Date**”) and continue through July 31, 2022 (the “**Initial Term**”). Notwithstanding the foregoing to the contrary, provided that Licensee shall not be in Default beyond any applicable notice and cure periods either at the time Licensor receives the Extension Notice (as hereinafter defined) or at the commencement of the Extension Term (as hereinafter defined), Licensee shall have the right to extend the Term of this Shared Space Arrangement for one (1) additional term of twelve (12) months (the “**Extension Term**”). Licensee must notify Licensor of its desire to extend the Term by providing written notice to Licensor (the “**Extension Notice**”) at least six (6) months prior to the Expiration Date. In the event of such extension, the “**Term**” shall include the Extension Term and such extension shall be upon the same provisions as for the Initial Term. In no event will the Term extend beyond the expiration of the Prime Lease.”

**2.Extension Term:** Licensee is hereby providing notice to Licensor that it is exercising its right to extend the Agreement for the Extension Term (as amended pursuant to this Amendment) and Licensor hereby accepts this Amendment as the Exercise Notice pursuant to Section 3(a) of the Agreement.

**3.Fees:** In consideration for the modifications in this Amendment, Licensee shall pay Licensor the full amount of the License Fee for the Extension Term (i.e., \$2,900,000) (the “**Pre-Paid Fees**”), within 30 days of the Effective Date (“**Outside Date**”). The receipt by Licensor of the Pre-Paid Fees is a material consideration for Licensor entering into this Amendment. If the Pre-Paid Fees are not received by Licensor on or before the

Outside Date, this Amendment will be void and of no further force or effect. For clarity, Licensee shall continue to pay the License Fee for the remainder of the Initial Term pursuant to the terms of the Agreement.

**4.No Default:** So long as Licensee surrenders the Shared Space at the expiration of the Extension Term in accordance with the terms and conditions set forth in the Agreement and the Prime Lease, Licensor shall pay Licensee, within 30 days after the expiration of the Extension Term, an amount equal to \$650,000

**5.("Surrender Payment")** for all furniture, fixtures and equipment owned by Licensee and used in the Shared Space (excluding any laboratory equipment that is not a fixture and is used in the Shared Space and owned by Licensee, which laboratory equipment shall remain the property of Licensee and shall be removed by Licensee at the expiration or earlier termination of the Agreement in accordance with the Agreement and the Prime Lease) (the "**Licensee FF&E**") and Licensee shall convey the Licensee FF&E to Licensor free and clear of all liens and other encumbrances. For the avoidance of doubt, the laboratory benches, hoods and other laboratory fixtures in the Shared Space shall not be removed by the Licensee.

**6.Governing Law.** This Amendment shall be governed by and construed under the laws of the State of Massachusetts, without giving effect to choice of law principles thereof that would cause the application of the laws of any other jurisdiction.

**7.Effect of Amendment.** Except as modified by this Amendment, the Agreement and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. In the event of any conflict between the terms contained in this Amendment and the Agreement, the terms herein contained shall supersede and control the obligations and liabilities of the parties.

**8.Successors and Assigns.** Each of the covenants, conditions and agreements contained in this Amendment shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns and sublessees. Nothing in this Section shall in any way alter the provisions of the Agreement restricting assignment or subletting.

**9.Miscellaneous.** This Amendment becomes effective only upon execution and delivery hereof by Licensor and Licensee. The captions of the paragraphs and subparagraphs in this Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof.

**10.Authority.** Licensor and Licensee each guarantees, warrants and represents that the individual or individuals signing this Amendment have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

**11.Counterparts; Facsimile and PDF Signatures.** This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. A facsimile or portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

[Signature Page Follows]

Licensor and Licensee, each by its duly authorized officer, have signed this Amendment No. 1 to the Shared Space Arrangement as of the Effective Date.

LICENSOR:

SENDA BIOSCIENCES, INC.,  
a Delaware corporation

By: /s/ Guillaume Pfefer  
Name: Guillaume Pfefer  
Title: CEO

LICENSEE:

OMEGA THERAPEUTICS, INC.,  
a Delaware corporation

By: /s/ Mahesh Karande  
Name: Mahesh Karande  
Title: President and CEO

Subsidiaries of the Registrant

**Entity Name**

Omega Therapeutics Security Corporation

**Jurisdiction of Incorporation**

Massachusetts

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement No. 333-258365 on Form S-8 of our report dated March 10, 2022, relating to the consolidated financial statements of Omega Therapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
March 10, 2022

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## CERTIFICATION

I, Mahesh Karande, certify that:

1. I have reviewed this Annual Report on Form 10-K of Omega Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) [omitted];
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

By: \_\_\_\_\_  
/s/ Mahesh Karande  
**Mahesh Karande**  
**President and Chief Executive Officer**





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

In connection with the Annual Report of Omega Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mahesh Karande, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 10, 2022

By: \_\_\_\_\_ /s/ Mahesh Karande  
**Mahesh Karande**  
**President and Chief Executive Officer**

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

In connection with the Annual Report of Omega Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Roger Sawhney, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 10, 2022

By: \_\_\_\_\_  
**/s/ Roger Sawhney**  
**Roger Sawhney**  
**Chief Financial Officer**

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