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, 2023

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	**81-3247585**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
140 First Street Suite 501 Cambridge, MA	**02141**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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

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

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

At June 30, 2023, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was approximately $140.2 million. Solely for purposes of this disclosure, shares of common stock held by executive officers, directors and certain stockholders of the Registrant as of such date have been excluded because such holders may be deemed to be affiliates.

The number of shares of Registrant's Common Stock outstanding as of March 21, 2024 was 55,154,985.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2024 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, 2023, are incorporated herein by reference in Part III.

Table of Contents

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, the sufficiency of our cash, cash equivalents and marketable securities to fund our operating expenses and capital expenditure requirements, our ability to continue as a going concern, 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.
- Volatility in capital markets and general economic conditions in the United States may be a significant obstacle to raising required funds. This and other factors raise substantial doubt about the Company's ability to continue as a going concern.
- 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.
- 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 candidate, OTX-2002, was cleared by the United States Food and Drug Administration to advance to clinical development. Clinical development of OTX-2002 may be delayed or terminated, and we may never obtain regulatory approval of OTX-2002, which may have a material adverse impact on our platform or our business. Furthermore, clinical development requires substantial capital investment, which we may not be able to support. We may incur unforeseen costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of OTX-2002 and our other product candidates.
- 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.
- Our ability to manufacture our epigenomic controller candidates, or EC candidates, for preclinical or clinical supply could be limited, especially with the increased demand for the manufacture of mRNA- and LNP-based therapeutics, which could adversely affect our development plans.
- Our EC 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 and supply 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, including drug supplies for combination therapy, 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 continue to evaluate plans 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. Any plan to establish our own manufacturing facility and infrastructure will be costly and time-consuming and we 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. Most of our product candidates are in preclinical development or discovery, and we recently received FDA clearance for our IND application for OTX-2002 and have initiated the associated clinical trial. 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.
- Third parties may obtain or control intellectual property rights that may prevent or limit the development of our technology or products. 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.

PART I

Item 1. Business.

Overview

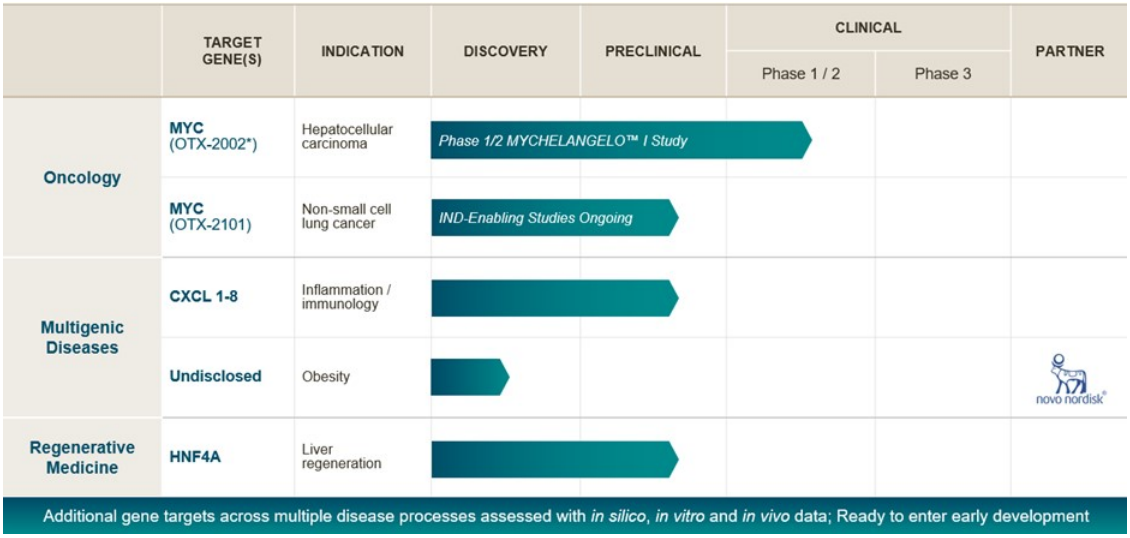
Omega Therapeutics is a clinical-stage biotechnology company pioneering a new class of programmable epigenomic mRNA medicines. Our OMEGA platform harnesses the power of epigenetics and our deep understanding of genomic architecture to precisely target and controllably modulate gene expression at the pre-transcriptional level to treat or cure diseases. 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 nature's innate control system for gene expression. 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, called epigenomic controllers, or ECs, to target EpiZips for precision epigenomic 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, including those with historically undruggable, intractable, and difficult-to-treat targets. Our pipeline currently consists of programs that span oncology, regenerative medicine, and multigenic diseases including immunologic and cardiometabolic conditions.

We believe that the precision epigenomic control delivered by the OMEGA platform has broad therapeutic applicability and transformational potential, spanning across:

- ***Oncology*.** Control of target oncogenes including historically challenging, auto-regulatory or un-druggable targets in various cancers.
- ***Multigenic diseases including immunologic and cardiometabolic conditions*.** 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.

Our Pipeline

Our current pipeline includes the following programs:



Intellectual Property and Manufacturing Capabilities

We have consolidated a significant intellectual property estate covering the OMEGA platform and our ECs 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 evaluating plans to build our own facility, to provide appropriate scale and quality to support development and commercialization of our ECs.

Our Strategy

Our objective is to become the leading programmable epigenomic medicines company by engineering, developing, manufacturing, and commercializing ECs, utilizing the OMEGA platform. Our vision is to treat and cure serious diseases by selectively and safely directing the human genome to control gene expression pre-transcriptionally without altering native DNA sequences.

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 proprietary ECs, expand our technologies, broaden our delivery capabilities, and enhance our institutionalized knowledge to further solidify our position as a leading digital and data-driven epigenomic medicines company. We plan to build additional computational, big-data, and advanced-analytic capabilities to maintain our leadership position. We plan to expand and strengthen our position as leaders in developing mRNA therapeutics for epigenomic control.
- ***Establish ECs as a new class of programmable epigenomic mRNA medicines.*** 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 ECs and to expand our repertoire of ECs that can be used for therapeutic applications. We have conducted *in vivo* preclinical studies of our ECs in multiple disease models for various indications, including hepatocellular carcinoma, or HCC,

non-small cell lung cancer, or NSCLC, and inflammatory diseases, including acute respiratory distress syndrome (ARDS) and in models of fibrosis, and we expect to conduct *in vivo* preclinical studies for multiple additional programs. We have initiated clinical development for the HCC program and IND-enabling studies for our NSCLC program.

- ***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 additional collaborations or co-development arrangements 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 EC 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.

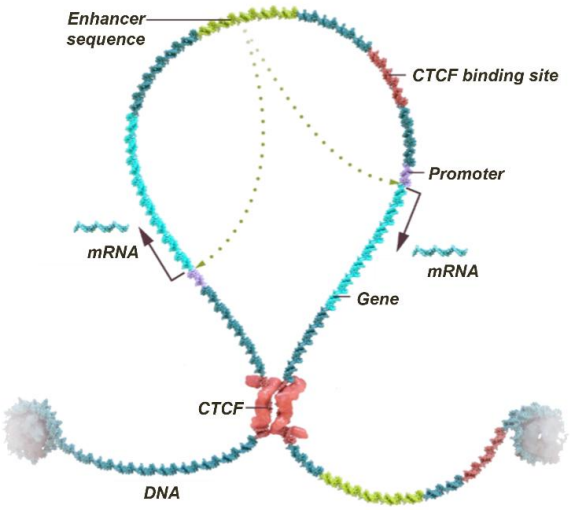
Background on Insulated Genomic Domains (IGDs)

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 approximately 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.

OMEGA Platform

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

The OMEGA platform is built on four foundational components:

1. Proprietary Database of IGDs and EpiZips as New Drug Targets

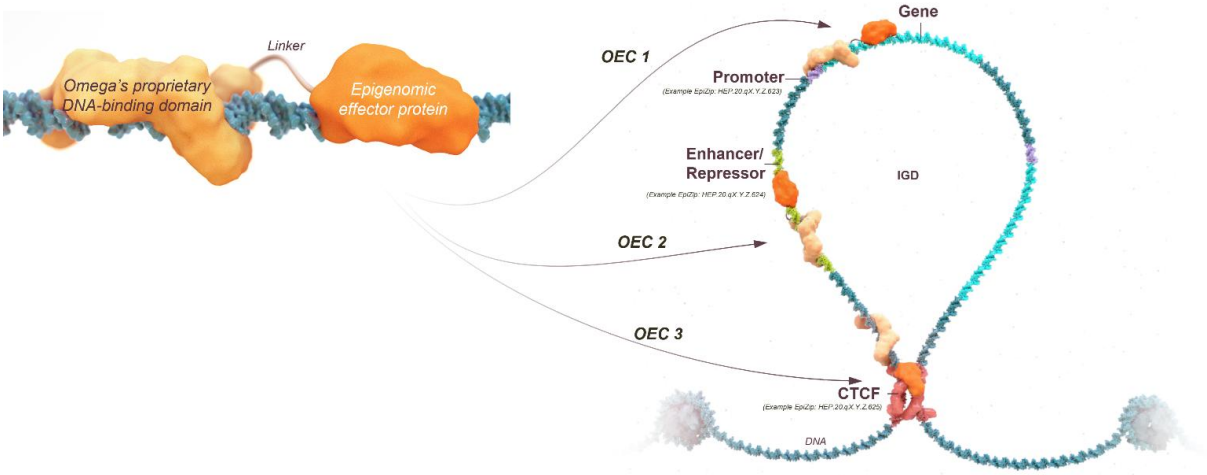
We utilize a biology-first approach to target identification starting with validated gene targets linked to a disease indication of interest. We use proprietary algorithms and machine-learning tools to mine our own and

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 ECs 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.

2. Programmable Epigenomic mRNA Medicines Tailored to Disease

We have created a modular basis for efficient and intelligent design of programmable epigenomic mRNA medicines, the ECs. These prospectively engineered investigational medicines allow us to regulate multiple genes with exquisite specificity, controllable tuning, and duration of effect. Our ECs are programmable mRNA therapeutics that express fusion proteins comprised of two components—a DNA-binding domain and an epigenomic effector protein, as shown in the figure below. The DNA-binding domain is designed to target a particular EpiZip with exquisite specificity. The epigenomic effector protein is designed to interact with DNA or DNA-associated proteins within the cell nucleus, such as histones and transcription factors, to up- or down-regulate gene expression and control the duration of effect. We use proprietary algorithms to design our ECs, including programming DNA-binding domains and selecting optimal epigenomic effector proteins. These computational tools allow us to efficiently generate numerous potential ECs and increases our ability to engineer ECs to treat a particular target.

Epigenomic Controller (EC)*



*mRNA medicines expressed as proteins in cell nucleus

We are currently developing proprietary zinc-finger-like proteins and other DNA-binding domains. For epigenomic effectors, we have generated and continue to build a library consisting of more than 100 single- and multi-functional epigenomic effector domains, including both naturally occurring and proprietary engineered variants of DNA-modifying factors, histone-modifying factors, and other chromatin-remodeling factors.

The initial identification of IGDs, EpiZips, and the mechanism of action for ECs directed to particular target genes are rapidly validated utilizing epigenomic controller screens. Our modular design approach allows us to accelerate our discovery process and to identify gene targets and generate initial lead ECs to modulate them in potentially as little as a few weeks.

3. Engineered, Customized Drug Delivery to Target Tissues and Cells

Delivery to the appropriate cells and tissues is critical to the successful application of our technology. We are exploring and innovating a multitude of delivery methods.

We have chosen lipid-nanoparticle-, or LNP-, delivery technology validated in third-party clinical trials for our initial programs. LNPs are currently used in products, both approved and in development. We have deep expertise in delivery formulations and leverage technological improvements and established regulatory precedents to develop our own LNPs. We are delivering our ECs as mRNA, which encodes the DNA binding domain and epigenomic effector proteins, encapsulated within a LNP. Our LNPs typically consist of 4- or 5-component molecules that encapsulate nucleic acids like mRNA, protect and transport payload 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 EC, 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. We are also expanding beyond LNP delivery technology and evaluating other delivery modalities for our future EC programs.

4. Industry-Leading Computational, Biological, and Genomic 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 ECs. We take a rational and streamlined approach to the development of programmable epigenomic 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 ECs 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 ECs, 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.

Our Development Programs

Our current pipeline is strategically focused on development programs in oncology, regenerative medicine, and multigenic diseases including immunologic and cardiometabolic conditions. The OMEGA platform has broad applicability across disease processes, including neoplasia, metabolic dysregulation, fibrotic processes, immune dysfunction, vascular pathology, and tissue degeneration. We have generated *in silico*, *in vitro* and *in vivo* data across a number of gene targets that we have the potential to advance into the clinic ourselves or through collaborations.

Oncology

OTX-2002 for Hepatocellular Carcinoma

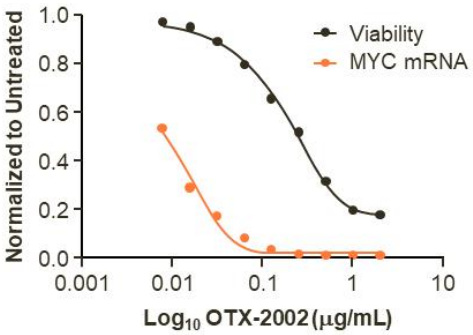
We are developing OTX-2002 to downregulate c-Myc, an oncogene that is dysregulated in more than 50% of human cancers and is frequently associated with poor prognosis, as a potential treatment for patients with advanced HCC. c-Myc has been shown to play a key role in liver tumor cell proliferation and is known to be upregulated 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, ECs 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.

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 and lenvatinib, 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.

When tested in a panel of HCC cell lines, OTX-2002 made epigenetic modifications in precisely targeted regions in the genome, leading to a reduction in MYC mRNA and protein levels and driving antiproliferative effects. In preclinical studies utilizing both subcutaneous and orthotopic mouse xenograft models of HCC, OTX-2002 led to significant tumor growth inhibition with no significant impact on body weight change in mice. The antitumor activity was consistent with reduction in MYC protein levels in the tumors. Further, in both in vitro and in vivo studies, OTX-2002 in combination with lenvatinib or sorafenib, the current standard of care agents in HCC, was associated with enhanced inhibition of tumor growth in HCC tumor models.

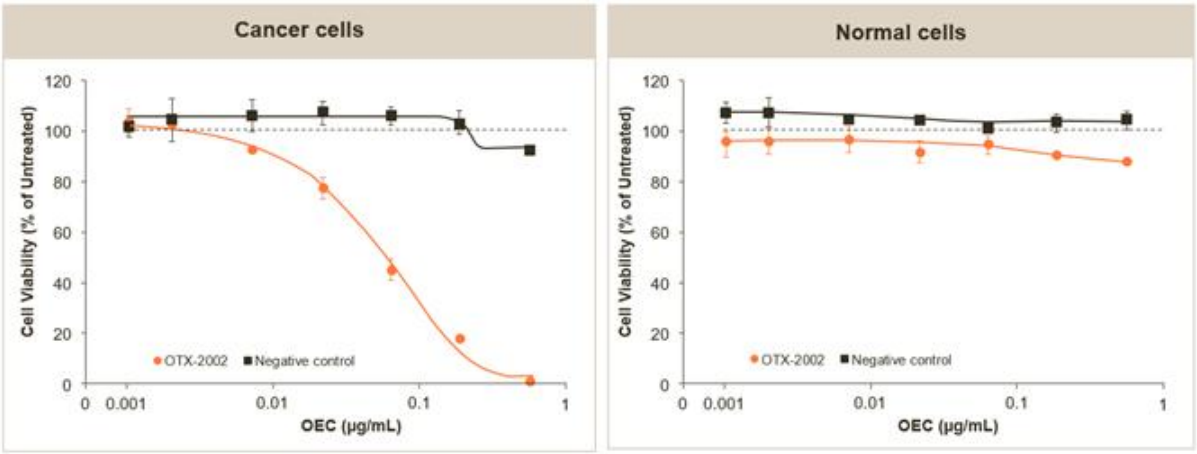
In a preclinical study of OTX-2002 in various HCC cell lines, OTX-2002 down-regulated c-Myc and we observed loss of cellular viability across targeted HCC subtypes with effects observed for 15 days. As shown in the graph below, the EC_{50}, which measures the concentration of a drug that provides a 50% response between baseline and the maximum response, was measured in HCC cell lines. Treatment with OTX-2002 resulted in a c-Myc mRNA expression EC_{50} 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)*



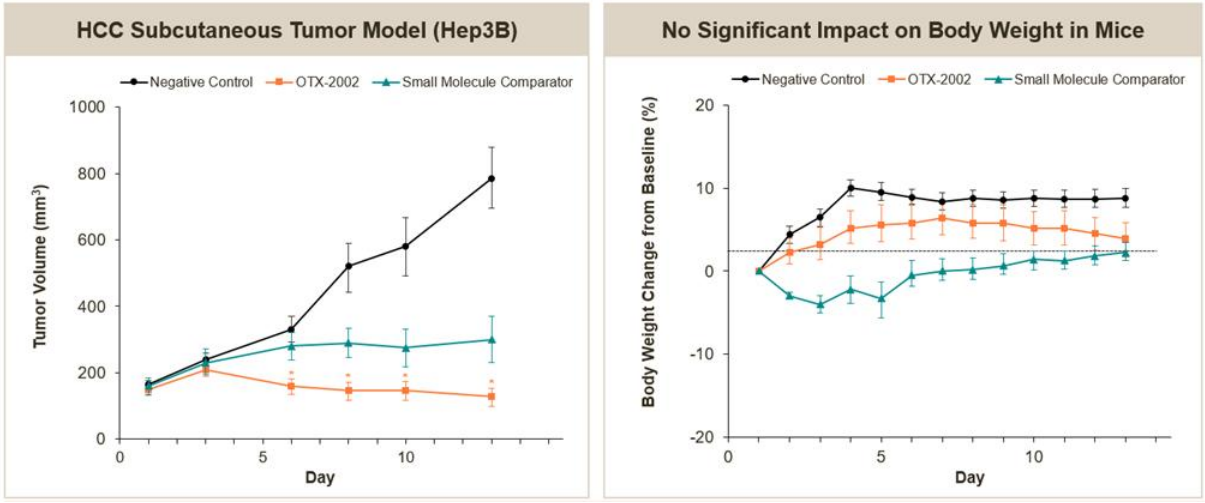
In a separate preclinical study of OTX-2002 in an HCC cell line (Hep3B), we demonstrated a selective effect on the viability of cancer cells. As shown in the graph below, treatment of cancer cells with OTX-2002 at concentrations ranging from 0.001 to 500 ng/mL resulted in a significant reduction in the viability of these cells, 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*)



OTX-2002 delivered via formulated LNPs in vivo decreased tumor burden in mice containing human HCC xenografts. In this preclinical study, we administered 3 mg/kg OTX-2002 every five days in a mouse subcutaneous tumor model or a small molecule control. As shown in the graph below, treatment with OTX-2002 was associated with a statistically significant inhibition of tumor growth, resulting in a 78% inhibition of tumor growth by Day 13 compared to the negative control. Treatment with OTX-2002 was equivalent to treatment with the small molecule comparator. Mice treated with OTX-2002 did not experience a significant decrease in body weight. OTX-2002 was well tolerated in this study with no adverse events observed.

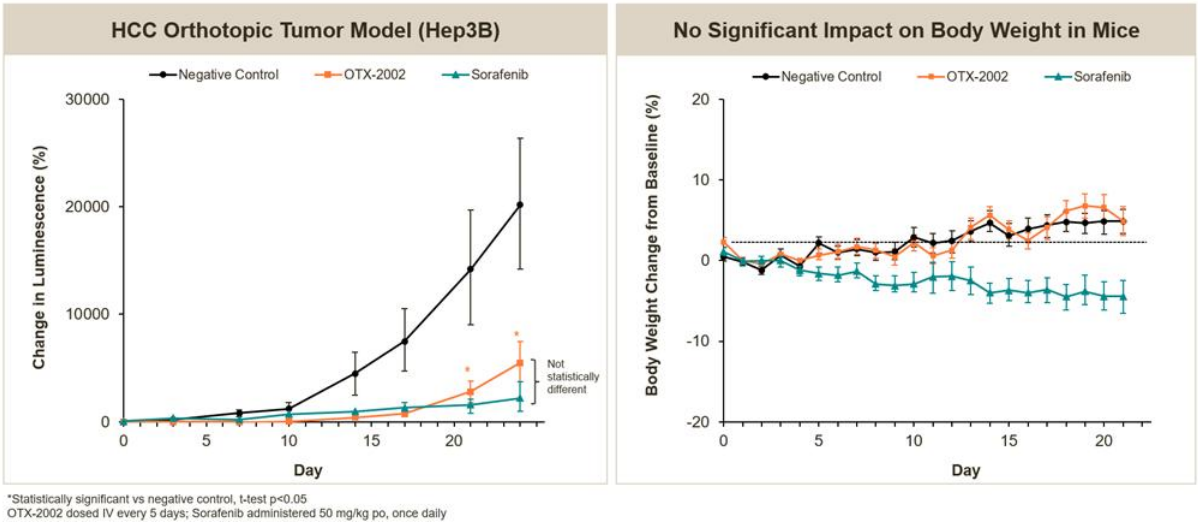
OTX-2002 anti-tumor activity observed in HCC subcutaneous xenograft model, with no significant impact on body weight *(in vivo)*



***Statistically significant vs negative control, t-test p<0.05 starting on Day 6. OTX-2002 dosed IV every 5 days**.

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.

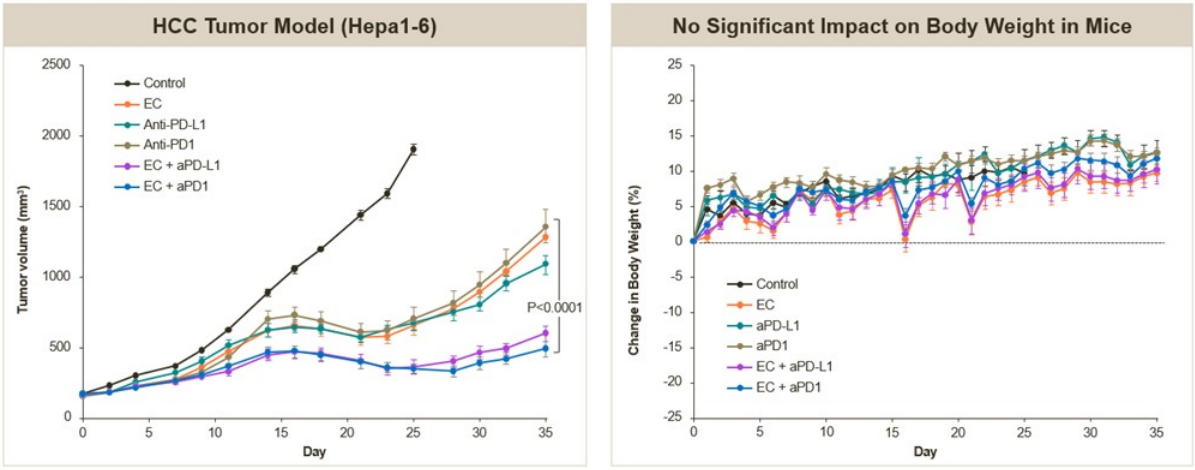
OTX-2002 anti-tumor activity and change in body weight observed in HCC orthotopic xenograft model (in vivo*)*



*Statistically significant vs negative control, t-test p<0.05
OTX-2002 dosed IV every 5 days; Sorafenib administered 50 mg/kg po, once daily

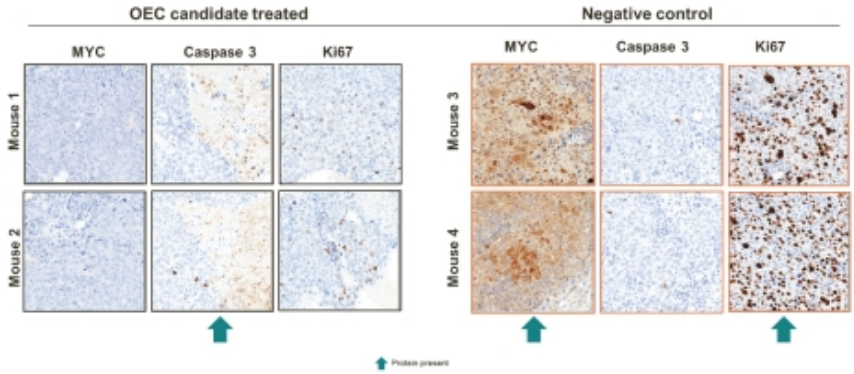
We have also observed statistically significant combination efficacy benefit with checkpoint inhibitors, including both anti-PD-1 and anti-PD-L1 agents. In evaluation of a mouse surrogate EC for OTX-2002 in a subcutaneous HCC tumor model (Hepa1-6), groups of immune competent mice were administered 1 mg/kg of the EC every five days, 10 mg/kg of either anti-PD1 or anti-PD-L1 weekly, combinations of the EC and anti-PD1 or anti-PD-L1, or a negative control. As shown in the graph below, combination treatment resulted in statistically significant inhibition of tumor growth compared to the negative control, and further, statistically significant inhibition of tumor growth compared to all of the monotherapy treatment arms. Both combination arms were well tolerated with no significant impact on body weight observed during the study.

Treatment with EC in combination with anti-PD1 or anti-PDL1 anti-tumor activity and body weight observed in HCC 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 EC candidate-treated and negative control tumors harvested from the animals in the *in vivo* studies described above showed significant downregulation of c-Myc protein in the tumors (indicated by loss of brown staining) as well as the expected downregulation 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 clinical biomarkers observed in HCC xenograft model



In July 2022, we announced clearance of our investigational new drug (“IND”) application from the United States Food and Drug Administration ("FDA") to initiate a Phase 1/2, first-in-human, clinical trial of OTX-2002 for the treatment of HCC.

In October 2022, we announced initiation of the Phase 1/2 MYCHELANGELO™I clinical trial. The global study is evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity of OTX-2002 as a monotherapy (Part 1) and in combination with standard of care therapies (Part 2) in patients with relapsed or refractory HCC and other solid tumor types known for association with the MYC oncogene.

In November 2022, we announced that OTX-2002 was granted Orphan Drug Designation by the FDA for the treatment of HCC.

In September 2023, we announced preliminary clinical data from the first two dose cohorts of the ongoing Phase 1/2 MYCHELANGELO I trial (NCT05497453), which is currently being conducted at clinical sites across the United States and Asia. As of the data cutoff of September 18, 2023, a total of eight patients were treated intravenously with either 0.02 mg/kg (dose level 1, n=4) or 0.05 mg/kg (dose level 2, n=4) of OTX-2002 once every two weeks. Changes in MYC DNA methylation and mRNA levels were analyzed through measurements of cell-free DNA and exosomal mRNA, respectively.

Key highlights from the preliminary clinical data from the first two dose levels of the trial, as of the data cut-off, include:

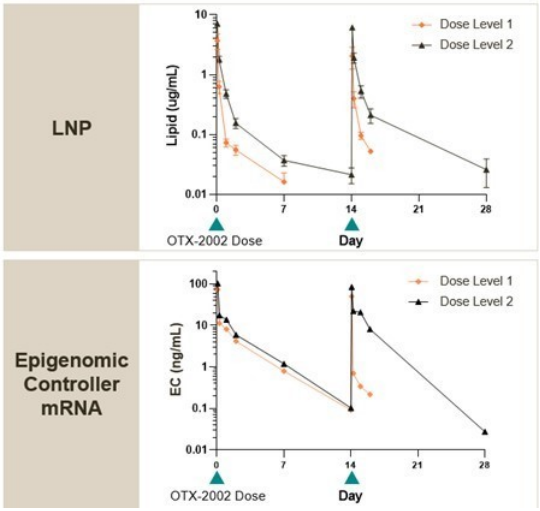
Safety and Tolerability:

- At both dose levels, OTX-2002 was generally well tolerated, with no dose-limiting toxicities.
- The majority of adverse events observed in the trial were grade 1 or 2.
- The most common treatment-related adverse events were infusion-related reactions (26%) including fever and chills, generally consistent with the known profile of other FDA-approved LNP-delivered therapeutics.

Pharmacokinetics:

- Consistent pharmacokinetic (PK) data across both dose levels with rapid clearance and minimal variability observed within and between patients.
- No accumulation was observed following repeat administration, and low, transient levels of immune response were observed with no related adverse events or impact on PK observed.

Predictable pharmacokinetics with rapid clearance of drug product observed

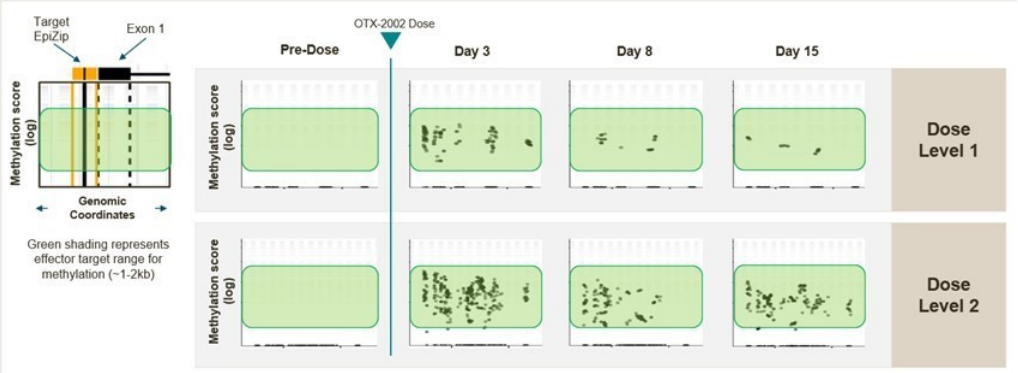


Translational:

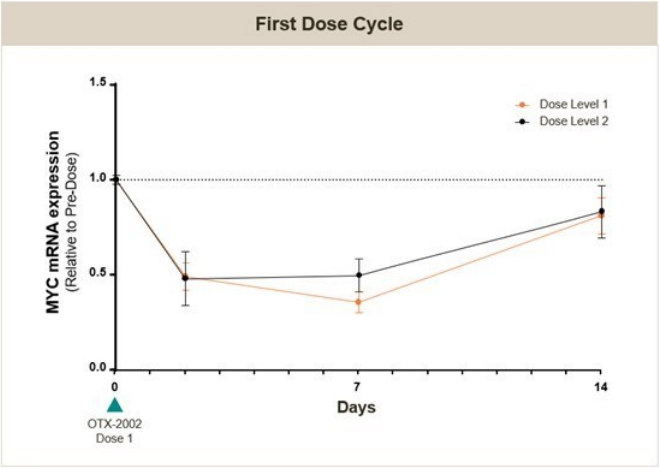
- Highly specific on-target engagement and intended epigenetic changes at the target genomic loci were observed for all eight patients across both dose levels, as evidenced by a robust, dose-dependent increase in cell-free DNA MYC methylation signal following administration with OTX-2002. The increased methylation signal persisted throughout the two-week dosing interval.

- Epigenetic modulation of MYC translated to rapid, robust and durable downregulation of MYC expression in exosomes in all eight patients, with mean reductions across both dose levels of approximately 55% observed 7 days following administration with OTX-2002.
- The increase in methylation and corresponding downregulation of MYC expression observed clinically are within the ranges that led to anti-tumor activity in preclinical xenograft models.

Highly-specific target engagement and intended epigenetic state change at target genomic loci within MYC IGD observed



Rapid, robust and durable downregulation of MYC mRNA expression observed



*Data represent mean expression data for all patients in each cohort (dose level 1, n=4; dose level 2, n=4)

In January 2024, we announced completion of the dose limiting toxicity (DLT) window for dose level 3 (0.06 mg/kg) in three patients with HCC. As of a data cut-off date of March 24, 2024, a total of eleven patients had been treated intravenously with either 0.02 mg/kg (dose level 1, n=4), 0.05 mg/kg (dose level 2, n=4) or 0.06 mg/kg (dose level 3, n=3) of OTX-2002 once every two weeks.

As of the data cut-off date, interim data from the first three cohorts showed:

- OTX-2002 continued to be generally well tolerated, with no dose-limiting toxicities observed. The majority of adverse events continued to be grade 1 or 2 (87%).
- Consistent dose-dependent pharmacokinetics with no drug accumulation observed following repeat doses. There was a low degree of variability in the PK profiles of both the LNP and

mRNA components, which were consistent both within and between patients as well as across dose levels.

- All patients demonstrated controlled modulation and downregulation of MYC expression, an important oncogene regulating cell function and cell death.
- The interim disease control rate (DCR) for HCC patients was 80%, reflecting 4 out of 5 efficacy-evaluable patients across the initial three dose levels having a best overall response of stable disease. These patients had an average of three or more previous therapies and entered the trial with a life expectancy of less than three months.

OTX-2002: Interim Monotherapy Overall Response Summary (as of March 24, 2024)

Best Overall Response	Participants with Non-HCC Solid Tumors (Dose Levels 1 & 2: 0.02-0.05 mg/kg) N = 5	Participants with HCC (Dose Levels 1-3: 0.02-0.06 mg/kg) N = 5*	Total N = 10*
Complete Response (CR)	0	0	0
Partial Response (PR)	0	0	0
Stable Disease (SD)	2 (40%)	4 (80%)	6 (60%)
Progressive Disease (PD)	3 (60%)	1 (20%)	4 (40%)
Objective Response Rate (ORR = CR + PR)	0	0	0
Disease Control Rate (DCR = CR + PR + SD)	2 (40%)	4 (80%)	6 (60%)

Interim data date of March 24, 2024. Patients who withdrew from the study for any reason other than progression were censored at date of last assessment. For participants with HCC, response assessed using mRECIST criteria.
*5 efficacy-eligible HCC patients from Cohorts 1-3. One patient in Cohort 3 discontinued treatment prior to their 6-week scan.

We believe that these interim data establish clinical proof-of-platform for Omega, highlight the potential of controlled epigenomic modulation with programmable mRNA candidates, and support the potential of epigenomic controllers as the next class of innovative therapeutics.

Based on these encouraging interim data, OTX-2002 continues to advance in monotherapy dose escalation and the Company is currently evaluating patients with HCC in cohort 4 at a dose level of 0.12 mg/kg. Cohort 4 completed the 28-day dose limiting toxicity window in early March 2024. The Company expects to report additional updated clinical data from monotherapy dose escalation in mid-2024. Following the identification of a recommended dose, the Company plans for expansion into monotherapy and combination settings in mid-2024.

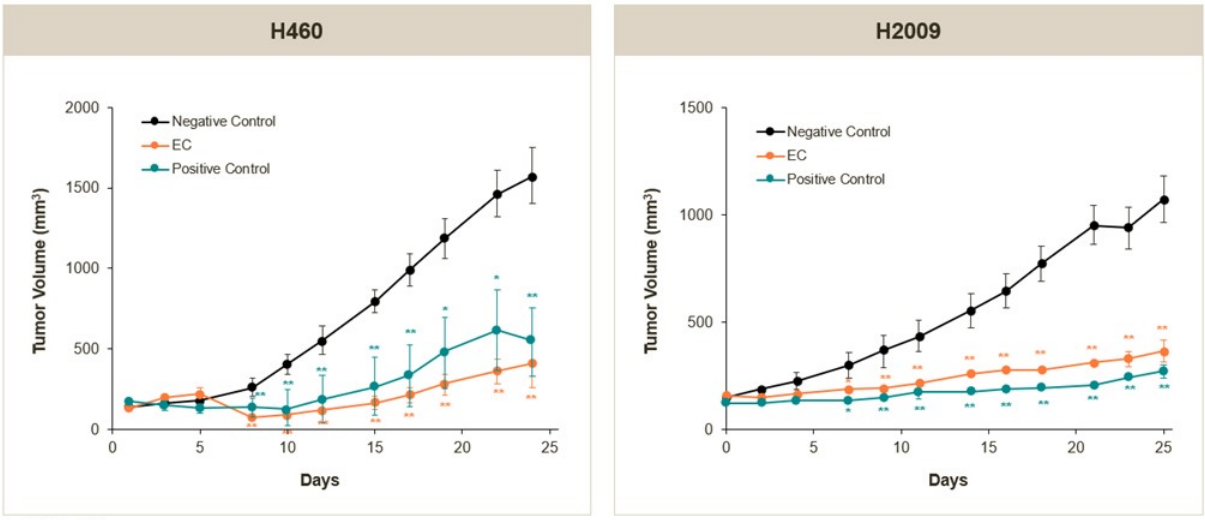
OTX-2101 for Non-Small Cell Lung Cancer

In October 2022, we announced the selection of OTX-2101 as a development candidate to advance into IND-enabling studies for the treatment of NSCLC. Approximately 50% of NSCLC tumors overexpress c-Myc. We are developing OTX-2101 to downregulate 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 EC 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. Importantly, in in vitro preclinical studies, minimal antiproliferative effects in normal primary lung epithelial cells, fibroblasts, and endothelial cells were observed with these EC candidates. In addition, the EC candidates showed synergistic effects on cell proliferation in a preclinical study when treated in combination with clinically relevant TKIs (data not shown). We also conducted preclinical studies in two subcutaneous xenograft models of NSCLC. In these studies, we treated mice with 3 mg/kg of one of our EC candidates every five days. Treatment with our MYC-targeting EC candidate showed a statistically significant reduction in tumor size during the dosing phase of the study, with no reduction in body weight of treated mice observed. In these two studies, treatment with our EC

candidate was associated with an equivalent effect on tumor volume to treatment with the standards of care (positive control), chemotherapy medication used to treat several cancers, as shown in the graphs below.

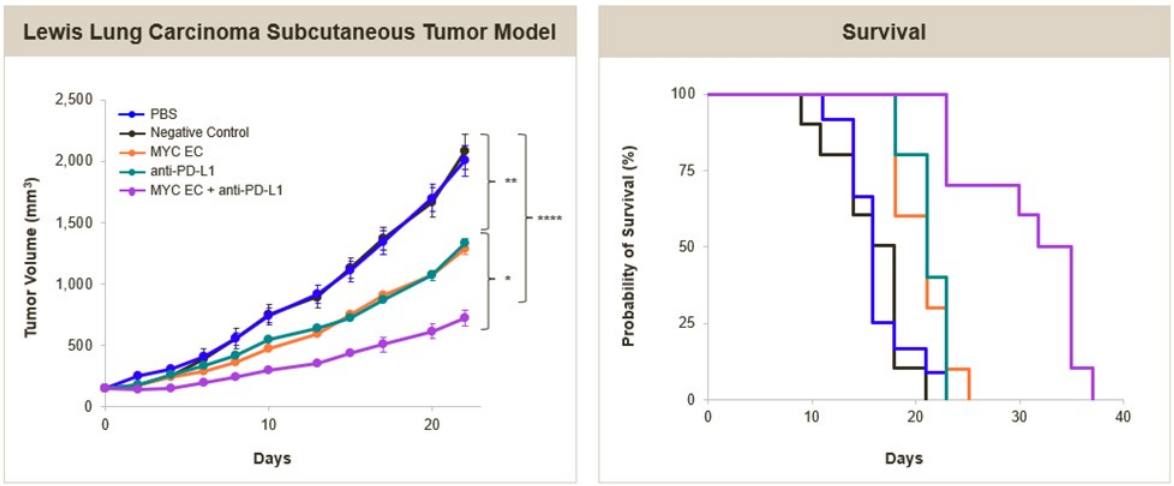
EC candidate anti-tumor activity in H460 and H2009 NSCLC subcutaneous xenograft models *(in vivo)*



*p<0.05; **p<0.01
EC dosed every five days

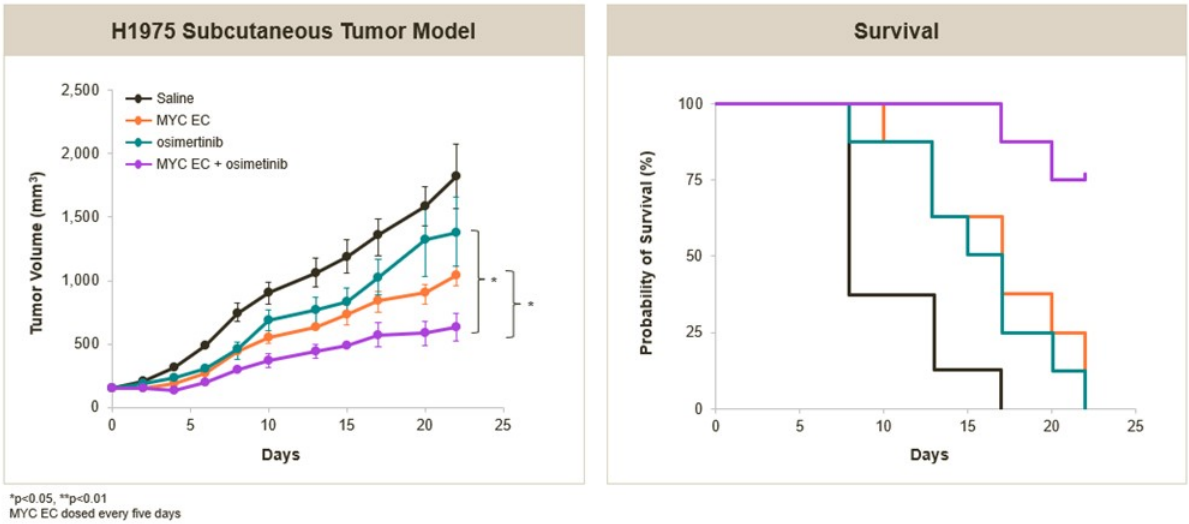
We further evaluated our MYC-targeting EC in preclinical combination settings with an immune checkpoint or EGFR inhibitor. Treatment with a MYC-EC plus an anti-PD-L1 antibody resulted in enhanced anti-tumor activity in a syngeneic mouse model of NSCLC, as shown below. Additionally, combination of MYC-EC with EGFR inhibitor, osimertinib, synergistically reduced tumor cell viability in vitro and significantly enhances tumor growth inhibition in vivo in a human xenograft model of NSCLC.

Combination of MYC-targeting EC with immune checkpoint significantly enhanced anti-tumor activity in syngeneic mouse model of NSCLC



*p<0.05, **p<0.01, ****p<0.0001
MYC EC dosed every five days

Combination of MYC-targeting EC with EGFR inhibitor significantly enhanced anti-tumor activity in human xenograft model of NSCLC



*p<0.05, **p<0.01
MYC EC dosed every five days

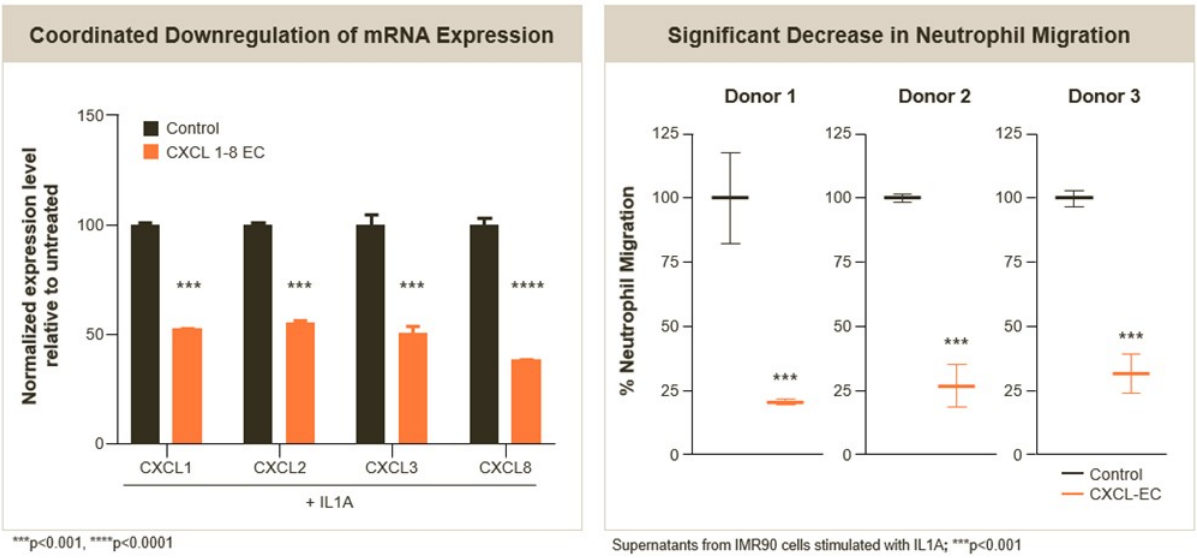
Collectively, these findings further support the potential of OTX-2101 for the treatment of advanced NSCLC as a monotherapy or in combination settings with standard of care therapies.

Multigenic Diseases Including Immunology

We are evaluating an EC candidate to reduce expression of the CXCL1, 2, and 3 and IL-8 gene cluster in various potential indications, including inflammatory lung diseases such as neutrophilic asthma and acute respiratory distress syndrome (ARDS), dermatological and rheumatological indications, and oncology. Overexpression of the CXCL gene cluster produces chemokines that attract neutrophils and promotes local inflammation. In the case of ARDS, chemokines that recruit inflammatory cells to the lung are of pivotal importance in disease pathogenesis 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%.

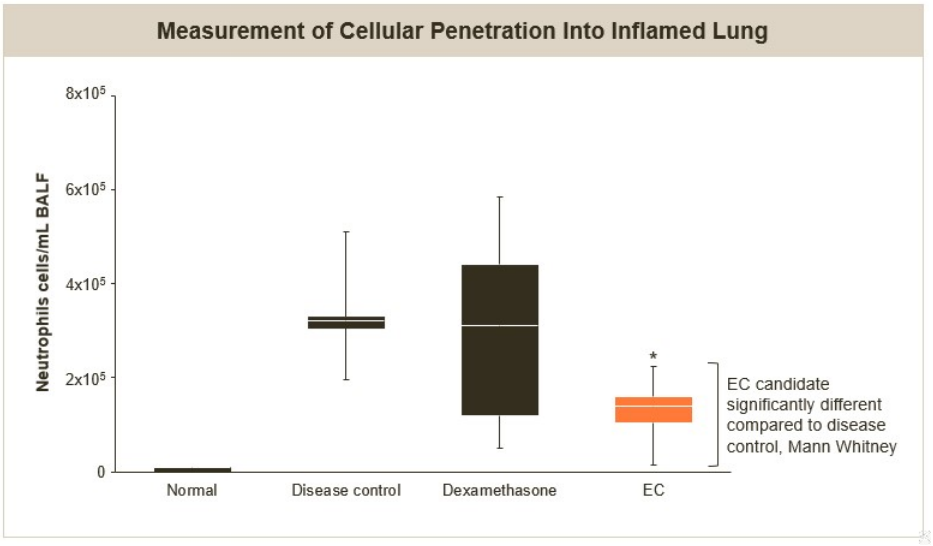
In a preclinical study of a CXCL 1-8-targeting EC candidate in human monocytes, at 24 hours post-dosing we observed a 65% decrease in gene expression of CXCL1, a 45-60% decrease in gene expression of CXCL1, CXCL2, CXCL3 and CXCL8 mRNA expression relative to control. Supernantants from the CXCL-EC-treated human lung fibroblasts demonstrated a significant decrease in neutrophil migration in vitro.

Multigenic IGD targeting of chemokine genes led to significant decrease in neutrophil migration *(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 EC candidate. Animals were administered 3 mg/kg of the EC candidate 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 EC 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 disease control***

Regenerative Medicine

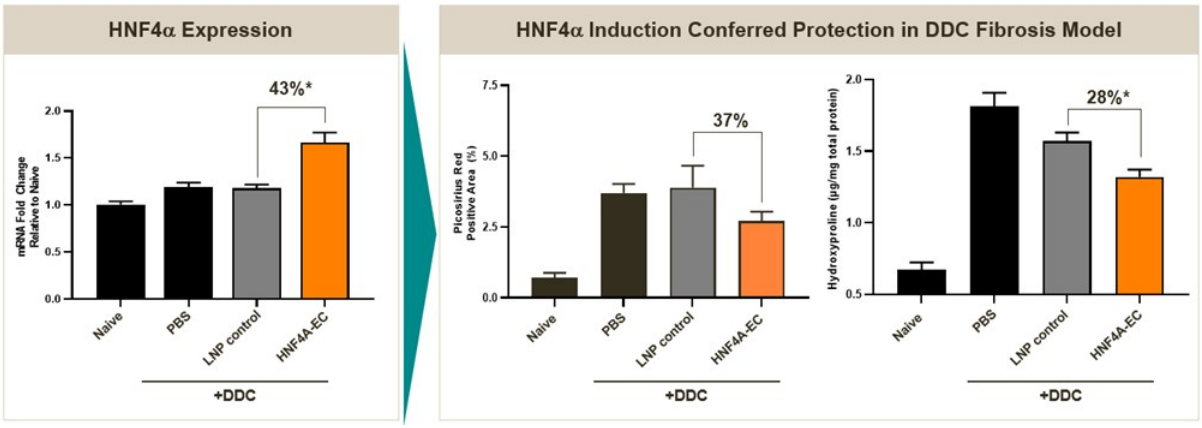
Liver Regeneration

We are developing EC candidates designed to increase expression of HNF4 , a transcriptional master regulator, as a potential way to restore liver-cell function in patients with severe liver dysfunction. HNF4 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, which are essential for normal liver function. In chronic liver disease, HNF4 is down-regulated, which contributes to the pathology of liver failure. Studies have shown that increased expression of HNF4 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 2019, in the United States, there were more than 13,000 people on the liver transplant waiting list and approximately 12% died before receiving a transplant.

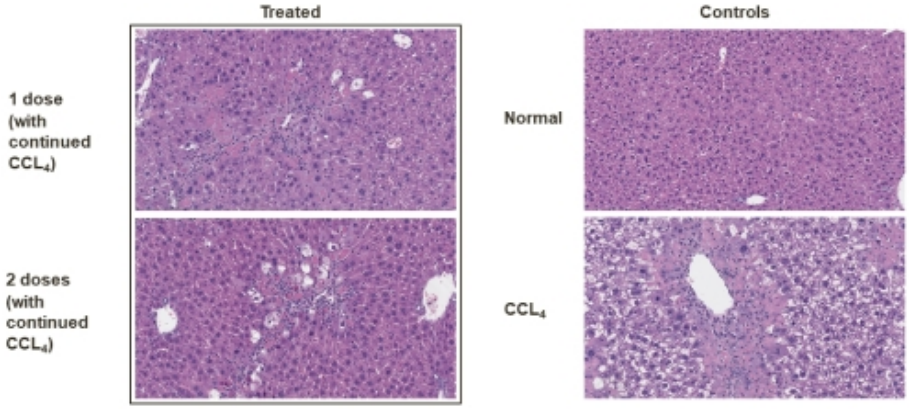
In preclinical studies in primary healthy human hepatocytes, treatment with a single dose of our EC candidate induced a durable increase in HNF4 for up to ten days, which we believe may be sufficient to return hepatocytes to a functional state and restore liver function in CLD and ESLD patients. We also observed that EC-mediated upregulation of HNF4α expression correlated with reduced expression of clinically relevant fibrotic genes in vitro, as shown in the graph below. These data support the proposed therapeutic mechanism of action of our EC candidate.

HNF4α-targeting EC significantly upregulated HNF4α expression and reduced key measures of fibrosis in preclinical models



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_4 in the images below). Treatment with a mouse surrogate construct of our EC candidate showed a significant decrease in hepatocellular degeneration on Days 31 and 38 with either one or two weekly administrations.

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



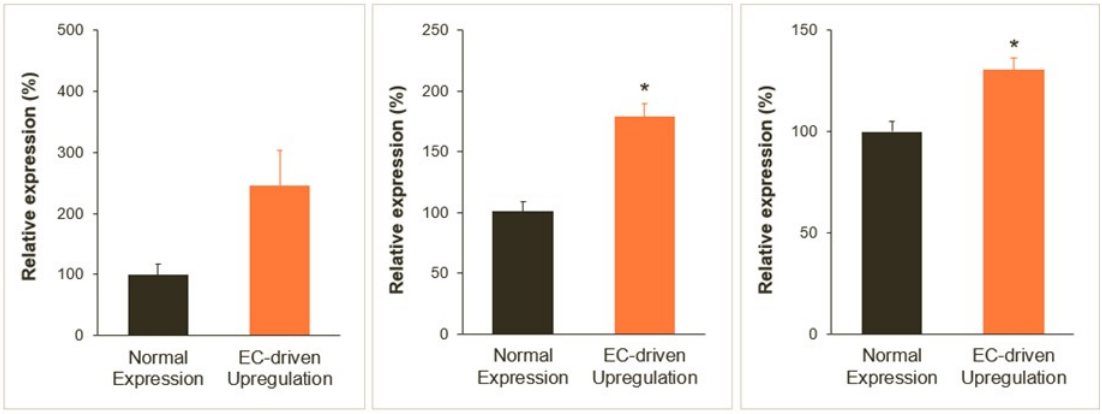
We are currently conducting additional *in vitro* and *in vivo* pharmacology, formulation optimization, efficacy, and preliminary safety studies of our EC candidate.

Translational Data

A critical element for the clinical translation of our EC candidates is our ability to design EC candidates that can target IGDs and tune gene expression across species. In preclinical studies, we evaluated changes in HNF4 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 EC candidate and in healthy mice treated with an EC candidate designed to target the homologous murine target sequence. As shown in the graph below, we observed therapeutically relevant up-regulation of HNF4 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 EC candidates and programs.

EC candidate increased HNF4α expression in preclinical studies (*in vivo*)

Species	Mouse	Nonhuman primate	FRG Mouse
Liver Cells	Mouse (48h)	Nonhuman primate (24h)	Human (24h)

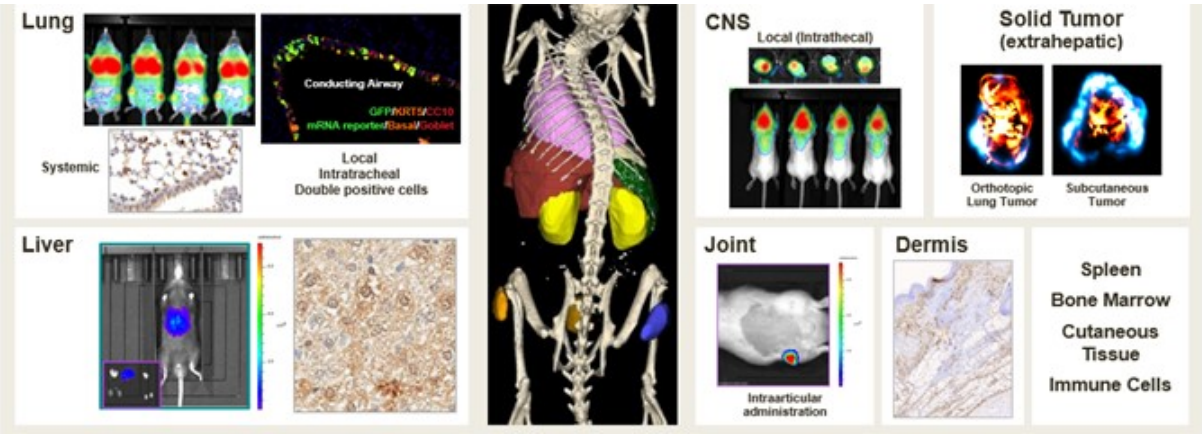


**** p<0.05 compared to negative control***

Delivery Data

Our Company has extensive internal expertise with formulation, delivery, and development of mRNA medicines. We are currently exploring a range of LNP and non-LNP formulations from various internal and external sources and have developed proprietary formulations that have shown specific and efficient *in vivo* functional delivery of our EC candidates to a number of therapeutically relevant cell and tissue-types in preclinical studies, as shown in the figure below. Our current library of delivery formulations access a variety of tissues and cell types, including liver (e.g. hepatocytes, stellate cells, Kupffer cells), and lung (e.g. endothelium, alveoli, epithelium). Leveraging momentum in delivery, we are also advancing our capabilities to reach 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). These delivery capabilities collectively enable us to develop and expand our pipeline.

Internal development efforts to develop proprietary LNPs and expand into additional tissues



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.

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 example, 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 collaborations with external partners 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 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 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 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., CRISPR Therapeutics AG, Editas Medicine Inc., Ionis Pharmaceuticals, Inc., Intellia Therapeutics, Inc., Janssen Pharmaceuticals, Inc., 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. / Ascletis 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 ECs 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, ECs, 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, ECs and our therapeutic programs. Our patent portfolio also covers our product candidates that are in development. As of December 31, 2023, our patent portfolio consists of 42 patent families. Among these families are 4 U.S. patents, 2 foreign patents in Europe and Japan, which will expire in 2037 or 2038. These patent families also include 38 pending U.S. patent applications (including both provisional and non-provisional applications), 94 pending foreign patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Japan, Korea, Mexico, New Zealand, Singapore, South Africa, and Taiwan, and seven owned or in-licensed Patent Cooperation Treaty (PCT) applications that have not entered national phase. Any U.S. or foreign patents issuing from or claiming priority to the pending patent applications in our patent portfolio will expire between 2037 and 2044, 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, ECs, delivery and manufacturing technology), inventions, improvements and current and future product candidates. Our patent portfolio currently includes one granted patent covering at least one 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 includes patent rights directed to compositions and methods of using ECs; 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. Intellectual property related to our OMEGA platform includes patent applications owned by us. As of December 31, 2023, we owned two provisional U.S. patent applications disclosing certain methods for epigenetically modulating expression of a target gene related to the OMEGA platform. We expect patents issuing from or claiming priority to these pending applications, if any, to expire in 2044, excluding any patent term adjustments or extensions.

We also in-license patents and patent applications related to our OMEGA platform from Flagship. As of December 31, 2023, we in-licensed from Flagship two issued U.S. patents, one provisional U.S. patent application, six non-provisional U.S. patent applications, and 30 foreign patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Japan, Korea, Mexico, New Zealand, Singapore, South

Africa, and Taiwan related to the OMEGA platform. We expect patents issuing from or claiming priority to these pending applications, if any, to expire between 2037 and 2041, excluding any patent term adjustments or extensions.

We also in-license patents and patent applications related to our OMEGA platform from WIBR. As of December 31, 2023, we in-licensed from WIBR one issued U.S. patent, two foreign patents in Europe and Japan, four non-provisional U.S. patent applications, and 11 foreign patent applications in Canada, China, Europe, Hong Kong, Japan, and Mexico disclosing certain methods and compositions for modulating methylation of a target gene related to the OMEGA platform. We expect patents issuing from or claiming priority to these pending applications, if any, to expire in 2037 or 2038, 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 or those owned by Nitto Denko Corporation, or Nitto, and in-licensed to us pursuant to an exclusive license agreement limited to a jointly developed drug candidate.

Delivery-related intellectual property

The patent portfolio for our delivery technology includes patent applications directed to LNP formulations, lipid molecules, 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, 2023, we owned seven provisional U.S. patent applications, two non-provisional U.S. patent applications, 10 foreign patent applications in Australia, Canada, China, Europe, Japan, and Korea, and two PCT patent applications related to delivery technology. We expect patents issuing from or claiming priority to these pending applications, if any, to expire between 2041 and 2044, excluding any patent term adjustments or extensions. As of December 31, 2023, we also in-licensed from Flagship one issued U.S. patent and one non-provisional U.S. patent application related to delivery technology. We expect patents issuing from or claiming priority to these pending applications, if any, to expire in 2037, excluding any patent term adjustments or extensions.

Disease-related intellectual property

The disease-related patent rights in our intellectual property portfolio provide coverage for ECs 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 ECs 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, 2023, we owned three provisional U.S. patent applications related to methods of treating c-Myc related cancers. We expect patents claiming priority to these pending patent applications, if any, to expire in 2044, excluding any patent term adjustments or extensions. As of December 31, 2023, we also in-licensed from Flagship one provisional U.S. patent application, one non-provisional U.S. patent application, seventeen foreign patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, India, Japan, Mexico, New Zealand, Singapore, South Africa, and Taiwan, and three PCT applications related to EC 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 2041 and 2044, excluding any patent term adjustments or extensions.

CXCL1, 2, 3, and IL-8

We are developing EC 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. As of December 31, 2023, we in-licensed from Flagship one PCT patent application and one foreign application in Taiwan relating to

EC compositions that target the CXCL 1-3/IL-8 IGD, and methods of treating inflammatory disorders, including rheumatoid arthritis. We expect patents issuing from or claiming priority to these pending patent applications, if any, to expire in 2043, excluding any patent term adjustments or extensions.

HNF4a

Our liver regeneration program targets the master transcriptional regulator HNF4a. We have developed EC candidates that increase expression of HNF4a to restore liver-cell function in patients with severe liver dysfunction. As of December 31, 2023, we owned one U.S. non-provisional patent application and six foreign patent applications in Australia, Canada, China, Europe, Hong Kong, and Japan related to EC compositions of matter and methods of treating liver disease. We expect patents issuing from or claiming priority to 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 EC compositions and their use for treating additional disorders that would benefit from upregulation or downregulation of gene expression.

As of December 31, 2023, we owned one non-provisional U.S. patent application and six foreign patent applications in Australia, Canada, China, Europe, Hong Kong, and Japan 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 in 2040, excluding any patent term adjustments or extensions.

As of December 31, 2023, we owned one non-provisional U.S. patent application and six foreign patent applications in Australia, Canada, China, Europe, Hong Kong, and Japan directed to compositions and methods of treatment for metabolic disorders. We expect patents issuing from or claiming priority to these pending applications, if any, to expire in 2040, excluding any patent term adjustments or extensions.

As of December 31, 2023, we owned one provisional U.S. patent application directed to compositions and methods of treatment for metabolic disorders by modulating expression of a target gene. We expect patents issuing from or claiming priority to this pending application, if any, to expire in 2044, excluding patent term adjustments or extensions.

As of December 31, 2023, we owned three provisional U.S. patent applications directed to compositions and methods of treatment for cancer by modulating expression of a target gene. We expect any patents claiming priority to these pending applications, if any, to expire in 2044, excluding any patent term adjustments or extensions.

As of December 31, 2023, we owned one non-provisional U.S. patent application and six foreign patent applications in Australia, Canada, China, Europe, Hong Kong, and Japan directed to compositions and methods of treatment for inflammatory disorders. We expect patents issuing from or claiming priority to these pending applications, if any, to expire in 2041, excluding any patent term adjustments or extensions.

As of December 31, 2023, we owned one PCT patent application directed to compositions and methods of treatments for alopecia. We expect patents claiming priority to this pending application, if any, to expire in 2042, excluding any patent term adjustments or extensions.

As of December 31, 2023, we owned one provisional U.S. patent application directed to compositions and methods of treatments for liver disease. We expect patents claiming priority to this pending application, if any, to expire in 2044, 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 (e.g., ECs) to modulate gene expression by targeting IGDs and specific compositions and methods directed to specific targets for the treatment of various disorders, such as disorders related to one or more of MYC, CXCL1, CXCL2, CXCL3, and IL-8. 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 modulation of one or more of MYC, CXCL1, CXCL2, CXCL3, and IL-8. As of December 31, 2023, the Foundational IP was expected to expire between 2037 and 2043. 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). 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 sublicenses, 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). With respect to the sale of licensed products by us, our affiliates or our sublicensees, WIBR is entitled to receive 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.

During the years ended December 31, 2023 and 2022, we incurred $0.2 million and less than $0.2 million of expenses, respectively, consisting of license maintenance fees and milestone payments.

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., EC 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 years ended December 31, 2023 and 2022, we incurred total expenses of $0.4 million and $1.9 million, respectively, 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.

Collaboration and License Agreement with Nitto

In October 2022, we entered into a Collaboration and License Agreement (the "Nitto Agreement") with Nitto, pursuant to which, among other things, Nitto granted us an exclusive, worldwide, royalty-bearing, fully transferable and fully sublicensable license under all intellectual property (the "Nitto Licensed IP") owned or controlled by Nitto relating to its LNP delivery technology.

Under the terms of the Nitto Agreement, we paid Nitto an upfront cash payment of $1.0 million. We are also required to make up to $83.0 million in future payments to Nitto based upon the achievement of specified development, regulatory and sales milestones. We are also obligated to pay to Nitto tiered, single-digit percentage royalties on a country-by-country basis based on net sales of the Licensed Product, subject to reduction in specified circumstances.

Unless earlier terminated, the Nitto Agreement will expire on a country-by-country basis when there are no further royalty payments owed by us to Nitto in such country with respect to the licensed product. Upon expiration of the applicable royalty term with respect to the licensed product in a country, the license will become fully paid-up, royalty-free, perpetual and irrevocable with respect to the licensed product in such country. The Nitto Agreement may be terminated by either party upon the other party's uncured material breach of the Nitto Agreement, by either party in the event of the other party's bankruptcy, insolvency or certain similar occurrences, by us at any time for any or no reason. During the year ended December 31, 2023, we recorded $0.9 million of research and development expenses consisting of material costs, costs of services performed by Nitto, and reimbursable costs.

Research Collaboration Agreement with Novo Nordisk

On December 31, 2023, we entered into a Research Collaboration Agreement (the "Novo RCA") with Novo Nordisk A/S ("Novo Nordisk"), Pioneering Medicines 08, Inc. ("PM SpinCo"), and, with respect to certain provisions set forth in the Novo RCA, Pioneering Medicines (NN), LLC ("Shareholder") and PM (NN) Explorations, Inc. ("PMCo NN" and together with PM SpinCo and Shareholder, the "PM Entities"), affiliates of Flagship Pioneering ("Flagship"). Under the terms of the Novo RCA, we granted to Novo Nordisk an exclusive, royalty-bearing, transferable license, with the right to grant sublicenses through multiple tiers, for certain of our intellectual property to conduct research and development activities under an agreed-upon research and development plan, together with the PM Entities, relating to a product candidate, or program target, for the prevention, treatment or control of a cardiometabolic disease, including diabetes, in humans throughout the world. In connection with the execution of the Novo RCA, we received an upfront nonrefundable payment of $5.1 million from Novo Nordisk and expect to receive approximately $21.6 million in cost reimbursement through 2027 to fund the related research and development activities. Novo Nordisk's obligations to pay royalties with respect to a licensed product and country will expire upon the latest of ten years following first commercial sale of a licensed product in such country, the expiration of the last-to-expire of certain valid patent claims applicable to such licensed product in such country, and the expiration of regulatory exclusivity for such licensed product in such country, subject to

certain royalty reduction and step-down provisions set forth in the Novo RCA. For more information, see Note 11 - Collaboration Agreements in the Notes to the consolidated financial statements appearing at the end of this Annual Report.

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. 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.

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 disease or condition 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 (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labelling purposes). 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 in which the clinical trial takes place, 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 for multi-center trials. 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. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) 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, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days, excluding clock stops. 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.

Under the above described procedures, in order to grant the MA, 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. MAs 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 a MA or accept an application to extend a 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 destination, 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 Trade and Cooperation Agreement, or TCA, was agreed between the UK and EU,

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 continues to follow the EU regulatory regime, but its national competent authority will remain the MHRA. On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the “Windsor Framework”. This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., GB and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

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 since Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. Until January 1, 2024, the MHRA may rely on a decision taken by the European Commission on the approval of a new (MA in the centralized procedure), in order to more quickly grant a new GB MA. A new international recognition framework will be put in place from January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new GB MA.

There is no pre-MA orphan designation in the UK. Instead, the MHRA reviews 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 or 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 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 that govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain non-U.S. laws 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, 2023, we had 93 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 clinical-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 $97.4 million and $102.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $334.6 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 and conducting 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 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 potentially 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 and February 2023 registered direct offering 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.

Our existing cash, cash equivalents and marketable securities as of December 31, 2023 will not be sufficient to fund all of our efforts that we plan to undertake. Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities as of December 31, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2025. 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. In addition, as noted below, we have identified conditions and events about our ability to continue as a going concern. 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 most 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. In addition, we maintain the majority of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Our future capital requirements depend on many factors, including:

- the scope, progress, results, and costs of our preclinical studies and clinical trials of OTX-2002 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 if we pursue plans 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.

Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.

We have incurred significant losses since our inception and have never generated revenue or profit from product sales, and it is possible we will never generate revenue or profit from product sales. As of December 31, 2023, we had cash and cash equivalents and marketable securities of $73.4 million. Based on our current operating plans, we believe we will have sufficient funds to meet our obligations into the first quarter of 2025. However, we will need to raise additional capital to fund our future operations and remain as a going concern. There can be no assurance that we will be able to obtain additional funding, including through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources on acceptable terms, if at all. To the extent that we raise additional capital through future equity offerings, the ownership interest of common stockholders will be diluted, which dilution may be significant. We cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us. In the event that we are unable to obtain any or sufficient additional funding, there can be no assurance that we will be able to continue as a going concern, and we will be forced to delay, reduce or discontinue our product development programs or consider other various strategic alternatives.

Moreover, these factors raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price

per share of our common stock, and it may be more difficult for us to obtain financing. If existing or potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments to reflect the possible inability of the Company to continue as a going concern within one year after the issuance of such financial statements. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

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, 2023, we had $19.0 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, 2027, subject to further extension to September 30, 2028. Repayment of the loan began on September 30, 2023, with monthly principal payments of $0.3 million plus interest, along with a closing payment of $4.0 million on September 30, 2027 if the maturity date is not extended to September 30, 2028. 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. 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. Most 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 only recently commenced clinical trials 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 ECs 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 trial 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, which 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 a have a material adverse impact on our platform or our business.

Most of our programs are in preclinical development. 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 of OTX-2002 may be delayed or terminated, and we may never obtain regulatory approval of OTX-2002, which may have a material adverse impact on our platform or our business. Furthermore, clinical development requires substantial capital investment, which we may not be able to support. We may incur unforeseen costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of OTX-2002 and our other 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.

In July 2022, we announced clearance of our IND application from the FDA to initiate a Phase 1/2, first-in-human, clinical trial of OTX-2002 for the treatment of HCC, which has launched under the MYCHELANGELO clinical program. We have not initiated or completed any other 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 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 in which the clinical trial takes place, 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 for multi-center trials. 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 trial 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. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

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 with specific 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 MHRA published its consultation outcome on March 21, 2023 in which it confirmed that it would update the existing legislation. The resulting legislative changes, which are yet to be published, will ultimately determine the extent to which the UK regulations align with the (EU) CTR. A decision by the UK not to closely align its regulations with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

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.

Furthermore, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for a revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory exclusivity, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council. The proposals may be substantially revised before adoption, which is not anticipated before early 2025. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

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 received orphan drug designation from the FDA for OTX-2002 for the treatment of HCC, and we may seek orphan drug designation for additional product candidates in the future, but we may be unable to obtain such designations or maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our product revenue, if any, to be reduced.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs or biologics intended to treat relatively small patient populations as orphan drug products. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, orphan drug designation entitles a party to financial incentives such as tax advantages and user fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs or biologics for rare diseases, regardless of whether the drugs or biologics are designated for the orphan use. In addition, if a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a seven year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease or condition for that time period, except in limited circumstances. If our competitors are able to obtain orphan drug exclusivity prior to us, for products that constitute the “same drug” and treat the same diseases or conditions as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

We have obtained orphan drug designation from the FDA for OTX-2002 for the treatment of HCC. We may seek orphan designation for certain of our future product candidates. However, we may be unsuccessful in obtaining orphan drug designation for these and may be unable to maintain the benefits associated with orphan drug designation. Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug for another disease or condition. Even after an orphan drug is granted orphan exclusivity and approved, the FDA can subsequently approve a later application for the same drug for the same condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, 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. Moreover, orphan-drug-exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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 biotechnology 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 ECs. 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 forgo 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, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, 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 developments with COVID-19, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. 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 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, 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 2031, 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. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services (CMS) Innovation Center which will be evaluation on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

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.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once the regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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 foreign requirements. 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. Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, 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, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. 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, which govern the privacy, processing and protection of health-related and other personal information. 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 has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act, or CPRA, went into effect on January 1, 2023 and significantly amends the CCPA. It imposes 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 also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. 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. Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our activities outside the United States may be subject to additional compliance requirements and generate additional risks of enforcement for noncompliance. For example, on May 25, 2018, the General Data Protection Regulation, or GDPR, went into effect and imposes strict requirements for processing the personal data of individuals within the EEA. For example, the GDPR applies extraterritorially, and requires us to make detailed disclosures to data subjects, disclose the legal basis on which we can process personal data, to obtain valid consent for collecting and processing personal data (including data from clinical trials), appoint data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides robust rights for data subjects, and adopt appropriate privacy governance, including policies, procedures, training, and data audit. It also imposes mandatory data breach notification and certain obligations on us when contracting with service providers. 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. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). 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, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union, or CJEU, states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework, or DPF, as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. The DPF also introduced a new redress mechanism for EU citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in future. We currently rely on the EU standard contractual clauses and the UK Addendum to the EU standard contractual clauses and the UK International Data Transfer Agreement and the DPF relevant to transfer personal data outside the EEA and the UK, including to the United States, with respect to both intragroup and third party transfers. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Additionally, since January 2021, we have had to comply with the GDPR and the United Kingdom GDPR, with each regime having the ability to fine up to the greater of €20 million (£17.5 million) or 4% of global turnover for violations. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF.

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. Most of our product candidates are in preclinical development or discovery and we received FDA clearance for our IND application for OTX-2002 and have initiated the associated clinical trial. 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 ECs. 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 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 trials or change their position on the acceptability of our trial designs 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.

We may face competition from new entrants to the epigenetic medicine space. We also 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 Alnylam Pharmaceuticals Inc., Beam Therapeutics, Inc., Biogen Inc., CRISPR Therapeutics AG, Editas Medicine, 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;
- international terrorism, political unrest and wars, which could delay or disrupt business activity, and if any conflict 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, 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

Our ability to manufacture our EC candidates for preclinical or clinical supply could be limited, especially with the increased demand for the manufacture of mRNA- and LNP-based therapeutics, 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 EC candidates. Vaccines to treat COVID-19 include mRNA vaccines and vaccines that utilize lipid excipients. Several vaccines for COVID-19 have been approved by the FDA. As a result, there is unprecedented demand on these CDMOs to manufacture COVID-19 vaccines and capacity for mRNA- and LNP-based therapeutics 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 ECs for our anticipated preclinical and clinical development, we may experience supply constraints and disruptions as manufacturers prioritize supply for COVID-19 vaccines over our ECs. 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 EC candidates or, if we obtain regulatory approval for our EC candidates, to commercialize them, could be materially adversely affected.

Our EC 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 EC 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 EC 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 ECs 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 EC candidates may prove to have a stability profile that leads to a lower than desired shelf life of the final approved EC, 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 EC 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 and supply 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, including drug supplies for combination therapy, 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 continue to evaluate plans to develop our own manufacturing facility, we expect to rely on third parties at least 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 continue to evaluate plans 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. Any plan to establish our own manufacturing facility and infrastructure will be costly and time-consuming, and we may not be successful.

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

We have entered into collaboration agreements and may in the future seek other collaborative relationships for the development and commercialization of our product candidates. For example, in November 2021, we entered into a five-year collaboration with PM (CF) Explorations, Inc., in October 2022, we entered into a Collaboration and License Agreement with Nitto Denko Corporation and, in December 2023, we entered into a Research and Collaboration Agreement with Novo Nordisk A/S, Pioneering Medicines 08, Inc. and other parties. Under these and any similar future arrangements with any third parties, we have or 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.

We may not be able to realize the benefit of our existing or future collaborations 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 parties may obtain or control intellectual property rights that may prevent or limit the development of our technology or products. 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, Acuitas Therapeutics, Inc., or Acuitas, and Nitto Denko Corporation, or Nitto, 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, Nitto, 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, Acuitas, and Nitto 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, finance, 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 and clinical 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, Joshua Reed, 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.

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 December 31, 2023, 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 24,284,625 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 $1.235 billion, subject to adjustment for inflation 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:

- 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 and intend to continue to do so in the future. In particular, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. 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 three years of audited financial statements 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, we are 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, 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 neither we nor our independent registered public accounting firm, as applicable, will 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 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 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 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 our internal control over financial reporting. 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, 2023, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $187.4 million and $180.4 million, respectively, which may be available to offset future taxable income, if any. As of December 31, 2023, we also had federal and state research and development credit carryforwards of $12.4 million and $4.9 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 information technology 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 information, including intellectual property, confidential information, preclinical and clinical trial information, proprietary business information, personal information, 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. 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. Even if we identify security incidents, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. 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. Any such material security breach could compromise our information technology systems 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 maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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 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 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 recently experienced extreme volatility and disruptions, including, for example, severely diminished liquidity and credit availability, rising interest and inflation rates, crises involving banking and financial institutions, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, or the United States enters a recession, 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 or recession. As a result, our business, results of operations and price of our common stock may be adversely affected.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

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 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on the industry-standard frameworks such as the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology environment;
- a security team principally responsible for managing (i) our cybersecurity risk assessment processes, (ii) our security controls, and (iii) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors who have access to our critical systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled “Risk Factors — Our business and operations may suffer in the event of information technology system failures, deficiencies, or intrusions which could materially affect our results.”

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (the “Committee”) oversight of cybersecurity and other information technology risks. The Committee oversees management’s implementation of our cybersecurity risk management program.

The Committee receives annual reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from internal security staff or external experts as part of the Board’s continuing education on topics that impact public companies.

Our management team, including Chief Financial Officer and Vice President of Data and Information Technology, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team's collective experience includes over ten years of leading cybersecurity oversight and conducting table-top exercises of incident response scenarios.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

Item 2. Properties.

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, in Cambridge, Massachusetts. Phase 1 of the lease began in May 2023 and Phase 2 of the lease began in August 2023. The lease term for each Phase ends fifteen years after the lease commencement date of each respective phase, 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
Executive Officers		
Mahesh Karande	51	President, Chief Executive Officer and Director
Joshua Reed	51	Chief Financial Officer
Thomas McCauley, Ph.D.	55	Chief Scientific Officer
Yan Moore, M.D.	57	Chief Medical Officer
Ling Zeng	55	Chief Legal and Administrative Officer
Non-Employee Directors		
Christian S. Schade	62	Chairman of the Board of Directors
Rainer Boehm	63	Director
Luke M. Beshar	65	Director
Elliott M. Levy, M.D.	65	Director
John Mendlein, Ph.D., J.D.	64	Director
Michelle C. Werner	48	Director
Mary T. Szela	60	Director
Richard A. Young, Ph.D.	69	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.

Joshua Reed has served as the Chief Financial Officer since May 2022. Prior to Omega, Mr. Reed served as the Chief Financial Officer at Aldeyra Therapeutics from July 2018 to May 2022, where he was responsible for finance, business development, investor relations, compliance, human resources, and information technology. During his time at Aldeyra, Mr. Reed led multiple capital raises, oversaw the company's interactions with current and prospective investors and managed all aspects of the company's financial processes, including quarterly and annual SEC filings. Prior to Aldeyra, Mr. Reed held a variety of finance roles of increasing responsibility at Bristol-Myers Squibb, most recently serving as Vice President and Head of Finance Operations for the United States and Puerto Rico from June 2016 to July 2018. While at Bristol-Myers Squibb, Mr. Reed also led financial planning and analysis and worked on various acquisitions, divestitures, alliances, and collaboration agreements. Earlier in his career, Mr. Reed held positions at JP Morgan Chase, Credit Suisse First Boston, and Chase Manhattan Bank. He also currently serves on the Board of Directors and as Chairman of the Audit Committee of Scholar Rock, a publicly traded biotechnology company. Mr. Reed received his Bachelor of Science in Finance from Rutgers University and his Master of Business Administration from the University of Michigan's Ross School of Business.

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.

Ling Zeng has served as the Chief Legal and Administrative Officer of our company since March 2022. From September 2020 to March 2022, Ms. Zeng recently served as Chief Legal Officer and Secretary at Dicerna Pharmaceuticals where she worked alongside other executives, the board of directors and their committees to develop and implement company strategy, policy, compliance, and governance activities. From August 2017 to September 2020, Ms. Zeng served as Deputy Head Legal, Group Mergers and Acquisitions, at Novartis AG, where she was responsible for global transactions across the Novartis Group, including all business units and regions. Prior to this, she served in various legal executive roles of increasing responsibility at Bausch Health Companies, Inc., Penwest Pharmaceuticals Co. and Barr Laboratories, Inc. Ms. Zeng began her legal career at Cleary, Gottlieb, Steen and Hamilton and, prior to that, also spent time as a researcher at Alkermes Inc. and LeukoSite Inc. Ms. Zeng earned her Bachelor of Science in Physics from Peking University, Master of Science in Biophysics from Brandeis University, and her Juris Doctorate from Georgetown University.

Non-Employee Directors

Christian S. Schade has served as a member of our Board since July 2023 and as Chairman of our Board since August 2023. Mr. Schade is a seasoned executive with over 30 years of experience across private and public biopharma companies, including proven leadership in several executive roles. He joined Flagship Pioneering as a Growth Partner in January 2023. From July 2016 to August 2022, he was President and Chief Executive Office of Aprea Therapeutics. Mr. Schade had served as a member of the Aprea Therapeutics' board since 2016 and as Chairman of the board from September 2020 until August 2023. Prior to Aprea, he held leadership positions at Novira, Omthera Pharmaceuticals and Medarex. In addition to industry expertise, Mr. Schade brings extensive corporate finance and capital markets experience from the investment banking industry, with roles at Merrill Lynch and JP Morgan Chase & Co. He has served on the board of directors of Integra LifeSciences, Inc. (Nasdaq: IART) since 2006. He received a Master of Business Administration from the Wharton School at the University of Pennsylvania and a Bachelor of Arts from Princeton University. We believe that Mr. Schade's extensive leadership experience in the biotechnology and investment bank industries qualifies him to serve on our Board.

Rainer Boehm has served as a member of our board of directors since September 2022. Mr. Boehm brings over 30 years of clinical and managerial experience to Omega. He held several senior management positions during his extensive tenure at Novartis Pharma AG and its predecessor, CIBA-Geigy, spanning from 1988 to 2017, most recently as Chief Commercial & Medical Affairs Officer. He was a key figure in the successful establishment of Novartis Oncology. He oversaw the launch and life cycle management of many blockbuster brands in different geographies globally, amongst them Femara, Zometa and Glivec in oncology, as well as Cosentyx and Entresto and the immunology and cardiovascular disease areas. Prior to joining Novartis, he served as unit head at the Psychiatric Hospital in Zwiefalten, Germany. Mr. Boehm currently serves on the boards of Cellectis SA (Nasdaq: CLLS), Humanigen Inc. (Nasdaq: HGEN) and previously served on the board of Nordic Nanovector S.A. from July 2018 to April 2022. He holds a medical degree from the University of Ulm in Germany, and a Master of Business Administration from Schiller University, Strasbourg Campus in France. Recently he commenced a Master of Public Health program at the Universities of Basel / Bern / Zurich in Switzerland. We believe that Mr. Boehm's significant leadership experience in the pharmaceutical 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. Since June 2021, Dr. Levy has served as a Senior Advisor at the Boston Consulting Group. Dr. Levy served as Senior Vice President of Global Development of Amgen from September 2014 to June 2020 and Senior Vice President of R&D Strategy and Operations from June 2020 to May 2021. He has also served on the board of directors of NuCana plc since November 2021 and Editas Medicine since April 2023. Dr. Levy received his M.D. from Yale University and his B.A. from Yale College. We believe Dr. Levy's extensive experience in the industry qualifies him to serve on our board of directors.

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 boards of directors of the following public companies: Kura Oncology, Inc. since November 2018, Prometheus Biosciences from March 2021 until June 2023, Coherus Biosciences from July 2014 to August 2021 and Alimera Sciences Inc. from June 2018 to March 2021. 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 board of directors of Syros Pharmaceuticals, Inc. since November 2011. In May 2012, he was elected to 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.

Michelle C. Werner, has served as a member of our Board since August 2023. She has over 20 years of biopharma experience spanning commercial and R&D responsibilities, and since April 2022 has served as the CEO of Alltrna, a biotechnology company, and CEO-Partner at Flagship Pioneering. Prior to her current role, Ms. Werner served as Worldwide Franchise Head, Solid Tumors at Novartis Oncology from July 2020 until April 2022, where she was responsible for delivering the disease area strategies across multiple tumors and led business development efforts. Prior to Novartis, she was a senior leader at AstraZeneca in several roles, including Global Franchise Head in Hematology and Head of U.S. Oncology from 2016 until July 2020. Ms. Werner previously spent 10 years at Bristol Myers Squibb in various roles in sales, marketing, and market access in both the U.S. and the U.K., and above market in Europe and Global almost exclusively in oncology. We believe that Ms. Werner's extensive leadership experience in the pharmaceutical industry qualifies her to serve on our Board.

PART II

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.

Holders

As of March 21, 2024, there were approximately 79 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

We did not make any sales of unregistered securities during the year ended December 31, 2023.

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 net proceeds of approximately $128.1 million from our IPO have been invested in capital preservation investments, which include interest bearing savings accounts, short-term and intermediate-term, investment-grade securities, interest-bearing instruments and U.S. government securities. 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 a clinical-stage biotechnology company pioneering a new class of programmable epigenomic mRNA medicines. Our OMEGA platform harnesses the power of epigenetics and our deep understanding of genomic architecture to precisely target and controllably modulate gene expression at the pre-transcriptional level to treat or cure diseases. 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 nature's innate control system for gene expression. 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, called epigenomic controllers, or ECs, to target EpiZips for precision epigenomic 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, including those with historically undruggable, intractable, and difficult-to-treat targets. Our pipeline currently consists of programs that span oncology, regenerative medicine, and multigenic diseases including immunologic and cardiometabolic conditions.

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 and initiating 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, 2023, we had cash, cash equivalents and marketable securities of $73.4 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. In February 2023, we completed a registered direct offering of common stock pursuant to which we issued and sold 6,920,415 shares of our common stock at a purchase price of $5.78 per share and secured approximately $39.7 million in net proceeds after deducting estimated offering expenses. In August 2023, we entered into an Open Market Sale Agreement (the "Sales Agreement"), with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $60.0 million in "at-the-market," or ATM, offerings under our Registration Statement on Form S-3 (File No. 333-268254) filed with the SEC on November 8, 2022, which was declared effective on November 18, 2022. During the year ended December 31, 2023, we did not sell any shares of common stock under the Sales Agreement.

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.

Recent Developments

On December 31, 2023, we entered into a Research Collaboration Agreement (the “Novo RCA”) with Novo Nordisk A/S (“Novo Nordisk”), Pioneering Medicines 08, Inc. (“PM SpinCo”), and, with respect to certain provisions set forth in the Novo RCA, Pioneering Medicines (NN), LLC (“Shareholder”) and PM (NN) Explorations, Inc. (“PMCo NN” and together with PM SpinCo and Shareholder, the “PM Entities”), affiliates of Flagship Pioneering ("Flagship"). Under the terms of the Novo RCA, we granted to Novo Nordisk an exclusive, royalty-bearing, transferable license, with the right to grant sublicenses through multiple tiers, for certain of our intellectual property to conduct research and development activities under an agreed-upon research and development plan, together with the PM Entities, relating to a product candidate, or program target, for the prevention, treatment or control of a cardiometabolic disease, including diabetes, in humans throughout the world. In connection with the execution of the Novo RCA, Novo Nordisk agreed to make an upfront cash payment of $10 million, up to $522 million in future development and sales milestone payments, and mid and high-single digit to low double-digit percentage royalties on net sales of the licensed product. These payments will be shared approximately equally between us and Shareholder. In January 2024, we received $5.1 million as our share of the upfront cash payment. Novo Nordisk’s obligations to pay royalties with respect to a licensed product and country will expire upon the latest of ten years following first commercial sale of a licensed product in such country, the expiration of the last-to-expire of certain valid patent claims applicable to such licensed product in such country, and the expiration of regulatory exclusivity for such licensed product in such country, subject to certain royalty reduction and step-down provisions set forth in the Novo RCA. For more information, see Note 11 - Collaboration Agreements in the Notes to the consolidated financial statements appearing at the end of this Annual Report.

Development Programs

OTX-2002

In July 2022, we announced clearance of our investigational new drug (“IND”) application from the United States Food and Drug Administration ("FDA") to initiate a Phase 1/2, first-in-human, clinical trial of OTX-2002 for the treatment of hepatocellular carcinoma, or HCC.

In October 2022, we announced the first patient was dosed in the MYCHELANGELO™ I clinical trial. The Phase 1/2 MYCHELANGELO I trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary antitumor activity of OTX-2002 as a monotherapy (Part 1) and in combination with standard of care therapies (Part 2) in patients with relapsed or refractory HCC and other solid tumor types known for association with the MYC oncogene. The study is expected to enroll patients at clinical trial sites in the United States, Asia, and Europe.

In November 2022, we announced that OTX-2002 was granted Orphan Drug Designation by the FDA for the treatment of HCC.

In March 2023, we entered into a Clinical Supply Agreement with Roche to evaluate OTX-2002 in combination with Roche’s anti-PD-L1 therapy, atezolizumab, in patients with advanced MYC-driven hepatocellular carcinoma as part of our Phase 1/2 MYCHELANGELO I clinical trial. Under the terms of this agreement, Roche will supply atezolizumab and Omega will evaluate the combination as part of the overall conduct of the trial.

In September 2023, we announced preliminary safety, tolerability, pharmacokinetic and translational data from the initial two dose level cohorts (n=8) from Part 1 of the ongoing MYCHELANGELO I trial. Highly specific on-target engagement and intended epigenetic changes at the target genomic loci were observed for all eight patients across both dose levels, as evidenced by a robust increase in cell-free DNA MYC methylation signal following administration with OTX-2002. This epigenetic modulation of MYC translated to rapid, robust and durable downregulation of MYC expression in all eight patients, with mean reductions across both dose levels of approximately 55% observed 7 days following administration with OTX-2002. At both dose levels, OTX-2002 was generally well tolerated, with no dose-limiting toxicities. Based on these preliminary data, OTX-2002 continues to advance in monotherapy dose escalation. We expect to report updated clinical data from monotherapy dose escalation in mid-2024. Additionally, we are planning for expansion into monotherapy and combination settings in mid-2024.

OTX-2101

In October 2022, we announced the selection of OTX-2101 as the second EC development candidate to advance into IND-enabling studies for the treatment of non-small cell lung cancer, or NSCLC.

Other EC programs

Beyond HCC and NSCLC, we continue to advance other ECs from the OMEGA platform through preclinical studies.

Significant Risks and Uncertainties Related to Macroeconomic Conditions

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including, for example, severely diminished liquidity and credit availability, rising interest and inflation rates, crises involving banking and financial institutions, declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. Unstable market and economic conditions and further disruption created by pandemics or international political unrest, war and terrorism may have serious adverse consequences on our business, financial condition and results of operations.

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 recognized through December 31, 2023 has been generated through our collaboration agreement with PM (CF) Explorations, Inc., or PMCo, an affiliate of Flagship entered into in November 2021, 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, preclinical development, and clinical 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, preclinical development, and clinical 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 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 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 also include in research and development expenses certain related party expenses for general consulting, as well as facility costs and sublease income with Flagship affiliates.

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 clinical trials for OTX-2002 and any of our other 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 also include in general and administrative expenses certain related party expenses related to payments made to Flagship for general consulting, and software licenses incurred on our behalf. In addition, we include facility costs and sublease income with Flagship affiliates.

We expect that our general and administrative expenses will increase in the future as we continue to support our 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.

Other income (expense), net

Interest income (expense), net

Interest expense primarily consists of interest payments as well as the amortization of the debt discount related to our loan and security agreement. Interest income consists of interest earned from our marketable securities and money market accounts.

Other income (expense), net

Other income (expense), net primarily consists of foreign exchange gains and losses on invoices paid, as well as remeasurement gains and losses associated with changes in the fair value of the success fee obligation related to our loan and security agreement, as amended. Until settlement, fluctuations in the fair value of our success fee obligation are based on the remeasurement at each reporting period.

Results of operations

Comparison for the years ended December 31, 2023 and 2022

The following table summarizes the results of our operations for the years ended December 31, 2023 and 2022, together with the changes in those items in thousands of dollars and as a percentage.

	Year Ended December 31,		$ Increase / (Decrease)	% Change
	2023	2022		
Collaboration revenue from related party	$ 3,094	$ 2,073	$ 1,021	49 %
Operating expenses:				
Research and development	77,169	81,167	(3,998)	(5)%
General and administrative	26,186	23,672	2,514	11 %
Total operating expenses	103,355	104,839	(1,484)	(1)%
Loss from operations	(100,261)	(102,766)	(2,505)	(2)%
Other income (expense), net:				
Interest income, net	2,810	222	2,588	NM
Other income (expense), net	23	(157)	180	NM
Total other income, net	2,833	65	2,768	NM
Net loss	$ (97,428)	$ (102,701)	$ (5,273)	

NM - Not meaningful

Revenue

Revenue of $3.1 million for the year ended December 31, 2023 and $2.1 million for the year ended December 31, 2022 consisted of reimbursement of research costs incurred in connection with the collaboration agreement with PMCo entered into in November 2021.

Research and development expenses

Research and development expenses decreased by $4.0 million to $77.2 million for the year ended December 31, 2023, from $81.2 million for the year ended December 31, 2022. The $4.0 million decrease was primarily driven by a decrease in external research costs of $9.2 million, external manufacturing costs of $5.5 million, consulting and professional fees of $0.8 million, and lab expenses of $0.6 million, partially offset by an increase in personnel-related expenses of $4.0 million, including stock-based compensation to support business growth, and facilities and other costs of $6.9 million.

General and administrative expenses

General and administrative expenses increased by $2.5 million to $26.2 million for the year ended December 31, 2023, from $23.7 million for the year ended December 31, 2022. The $2.5 million increase was primarily driven by an increase in professional and consulting fees of $1.4 million, as well as facilities and other administrative costs of $1.1 million.

Interest income

Interest income was $2.8 million for the year ended December 31, 2023 and $0.2 million for the year ended December 31, 2022. The $2.6 million increase in interest income, net was attributed to an increase in interest income earned on marketable securities and money market accounts during the year ended December 31, 2023 due to an increase in interest rates.

Other expense, net

Other expense, net was income of less than $0.1 million for the year ended December 31, 2023 and an expense of $0.2 million for the year ended December 31, 2022. The increase in other income, net for the year ended December 31, 2023 was primarily due to a gain on disposal of fixed assets.

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 registered direct offering, and borrowings under our loan and security agreement.

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. In February 2023, we completed a registered direct offering of common stock pursuant to which we issued and sold 6,920,415 shares of our common stock at a purchase price of $5.78 per share and secured approximately $39.7 million in net proceeds after deducting estimated offering expenses.

In August 2023, we entered into the Sales Agreement, with Jefferies as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $60.0 million in "at-the-market," or ATM, offerings under our Registration Statement on Form S-3 (File No. 333-268254) filed with the SEC on November 8, 2022, which was declared effective on November 18, 2022. Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Global Select Market or on any other existing trading market for our common stock or to or through a market maker. During the year ended December 31, 2023, we did not sell any shares of common stock under the Sales Agreement.

Cash flows

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

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (91,510)	$ (98,515)
Net cash provided by (used in) investing activities	47,515	(18,060)
Net cash provided by financing activities	41,823	708
Net change in cash, cash equivalents, and restricted cash	$ (2,172)	$ (115,867)

Operating activities

Net cash used in operating activities totaled $91.5 million for the twelve months ended December 31, 2023 compared to net cash used in operating activities of $98.5 million for the twelve months ended December 31, 2022. The $7.0 million decrease in operating cash outflows was primarily attributable to $5.3 million in lower net loss recognized during the year ended December 31, 2023.

Investing activities

Net cash provided by investing activities totaled $47.5 million for the year ended December 31, 2023 compared to net cash used in investing activities of $18.1 million for the year ended December 31, 2022. The increase in cash provided by investing activities was primarily attributable to higher proceeds from maturities of marketable securities of $28.8 million and lower purchases of marketable securities of $37.6 million.

Financing activities

Net cash provided by financing activities for the year ended December 31, 2023 consisted primarily of $39.7 million of proceeds from our registered direct offering in February 2023, net of issuance costs and $2.6 million of proceeds from the lease financing transaction. Net cash provided by financing activities for the year ended December 31, 2022 consisted of $0.7 million in proceeds from the exercise of stock options. See Thermo Furniture Sale-Leaseback in Note 9 – Commitments and contingencies in the Notes to the consolidated financial statements appearing at the end of this Annual Report for more information about the sale-leaseback financing transaction.

Loan and security agreement

On March 9, 2018, we entered into a Loan Agreement with Pacific Western Bank (“PWB”) to initially borrow $8.0 million, which was further amended on September 30, 2019 (the "First Amendment"), January 22, 2020 (the "Second Amendment"), December 30, 2020 (the “Third Amendment”), and December 20, 2021 (the "Fourth Amendment").

On September 22, 2023, we entered into another amendment to the Loan Agreement (the "Fifth Amendment"), in which PWB extended the maturity date of the loan to September 30, 2027, subject to further extension to September 30, 2028 upon receipt by us on or before December 31, 2024 of at least $50.0 million of cash proceeds from the sale of its equity securities and/or non-refundable upfront strategic partnership proceeds. Repayment of the loan began on September 30, 2023, with monthly principal payments of $0.3 million plus interest, along with a closing payment of $4.0 million on September 30, 2027 if the maturity date is not extended to September 30, 2028. Interest will continue to be determined at a floating annual rate equal to the greater of (i) 0.50% above the prime rate then in effect and (ii) 5.50%. We 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. Under the terms of the Fifth Amendment, we are required to pay a success fee of $0.1 million pursuant to the Fifth Amendment, in addition to the $0.2 million success fee obligation pursuant to the Fourth Amendment. The success fees are contingent on achieving specified liquidity events. We determined that the success fee obligation represented a freestanding financial instrument, and it was classified as a liability on our consolidated balance sheet 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.

In addition, pursuant to the Fifth Amendment, we agreed to maintain with PWB, at all times, a balance of at least $5.0 million of unrestricted cash, subject to termination upon our prepayment of outstanding loans in an aggregate amount of at least $5.0 million or if the principal balance of the loans is less than $10.0 million.

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 until maturity.

As of December 31, 2023, we had cash, cash equivalents and marketable securities of $73.4 million. We expect that our expenses will increase substantially in connection with our ongoing activities, particularly as we advance preclinical activities and conduct clinical trials for OTX-2002 and any other 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 clinical trials of OTX-2002 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; and
- the costs of operating as a public company.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2025. However, 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. We have had recurring losses since inception and we expect to continue to generate operating losses and use cash in operations for the foreseeable future. We expect to finance our 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. Volatility in capital markets and general economic conditions in the United States may be a significant obstacle to raising the required funds

and, as a result, we may be unable to secure the necessary funding on acceptable terms. This raises substantial doubt about our ability to continue as a going concern.

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, Acuitas and Nitto Denko Corporation, 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, we are obligated to repay $0.3 million of principal plus interest per month beginning on September 30, 2023, along with a closing payment of $4.0 million on September 30, 2027 if the maturity date is not extended to September 30, 2028. As of December 31, 2023, the remaining amount of principal was $19.0 million.

We have office and laboratory space which is 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 was fully subleased to two other parties, which are affiliates of Flagship. One of the sublease agreements terminated in May 2022, and the other sublease agreement expires in September 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 140 First Street, Cambridge, Massachusetts, 02142. The term of the Lease commenced in May 2023 for Phase 1 and August 2023 for Phase 2, and ends fifteen years after lease commencement, subject to certain extension rights. The base rent for the leased space is $116.00 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. In July 2023, we entered into Shared Space Arrangements with affiliates of Flagship to sublease office and laboratory space located at 140 First Street, Cambridge, Massachusetts 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 policy is the 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 and clinical development activities, CROs in connection with clinical development and 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 and clinical studies 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.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued accounting pronouncements and have determined that, other than as disclosed in Note 2 - Summary of Significant Accounting Policies in the Notes to consolidated financial statements appearing at the end of this Annual Report, such standards will not have a material impact on our financial statements or do not otherwise apply to our current operations.

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, 2023, 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, 2023, our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

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

Changes in Internal Control over Financial Reporting

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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a). In order to ensure sufficient resources to advance its lead program and maximize near- and long-term value creation opportunities from its platform, the Company announced a strategic prioritization in March 2024. As part of this initiative, the Company streamlined the organization and optimized its R&D efforts and cost structure to extend its cash runway into the first quarter of 2025.

(b). Recently, the Company engaged in confidential discussions with certain investors regarding the possibility of raising equity in a public offering. At this time, in light of current market conditions, the Company has determined not to proceed with such financing. The Company will continue to evaluate its cash needs and business outlook, and it may seek additional financing in the future if it considers market conditions favorable.

(c). During the fourth fiscal quarter of 2023, no director or officer, as defined in Rule 16a-1(f) of the Exchange Act, adopted or terminated a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) or a "non-Rule 10b5-1 trading arrangement," as defined in Item 408 of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics, or Code, which 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. 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 2024 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 2024 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, 2023)

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)
Equity compensation plans approved by security holders (1)	8,780,737 (2)	$ 5.69 (3)	4,019,697 (4)
Equity compensation plans not approved by security holders	—	—	—
Total	8,780,737		4,019,697

(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 3,902,063 outstanding options to purchase stock under the 2017 Plan and 4,878,674 outstanding options to purchase stock under the 2021 Plan.

(3) As of December 31, 2023, the weighted average exercise price of outstanding options under the 2017 Plan was $3.13 and the weighted average exercise price of outstanding options under the 2021 Plan was $7.73.

(4) Includes 2,581,038 shares available for future issuance under the 2021 Plan and 1,438,659 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 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 2024 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 2024 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 2024 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			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
3.1	Restated Certificate of Incorporation.	8-K	001-40657	3.1	08/03/2021	
3.2	Amended and Restated Bylaws.	8-K	001-40657	3.1	12/11/2023	
4.1	Specimen Certificate of Common Stock.	S-1/A	333-257794	4.2	07/26/2021	
4.2	Amended and Restated Investor Rights' Agreement, dated March 4, 2021.	S-1/A	333-257794	4.1	07/26/2021	
4.3	Amended and Restated Warrant to Purchase Stock issued to PacWest Bankcorp, dated September 30, 2019, to purchase Series A preferred stock.	S-1/A	333-257794	4.3	07/26/2021	
4.4	Description of Capital Stock.	10-K	001-40657	4.4	03/10/2022	
10.1#	Form of Indemnification Agreement between Omega Therapeutics, Inc. and its directors and officers.	S-1/A	333-257794	10.8	7/26/2021	
10.2#	2021 Incentive Award Plan and form of agreements thereunder.	S-1/A	333-257794	10.2	7/26/2021	
10.3#	2021 Employee Stock Purchase Plan.	S-1/A	333-257794	10.3	7/26/2021	
10.4#	Non-Employee Director Compensation Program.	S-1/A	333-257794	10.4	7/26/2021	
10.5#	Employment Agreement by and between Mahesh Karande and the Registrant, dated July 25, 2021.	S-1/A	333-257794	10.17	7/26/2021	
10.6#	Employment Agreement by and between Thomas McCauley and the Registrant, dated July 24, 2021.	S-1/A	333-257794	10.18	7/26/2021	
10.7#	Employment Agreement by and between Yan Moore and the Registrant, dated December 12, 2021.	10-K	001-40657	10.8	3/10/2022	
10.8#	Employment Agreement by and between Ling Zeng and the Registrant, dated March 18, 2022.	10-Q	001-40657	10.3	05/04/2022	
10.9#	Employment Agreement by and between Joshua Reed and the Registrant, dated April 28, 2022.					*
10.10#	Consulting Agreement by and between Richard A. Young and the Registrant, dated November 7, 2016.	10-K	001-40657	10.9	03/10/2022	
10.11#	Amendment to Consulting Agreement by and between Richard A. Young and the Registrant, dated October 29, 2021.	10-K	001-40657	10.1	03/10/2022	

10.12#	Amendment to Consulting Agreement by and between Richard A. Young and the Registrant, dated October 5, 2022.					*
10.13#	Amendment to Consulting Agreement by and between Richard A. Young and the Registrant, dated October 6, 2023.					*
10.14	Loan and Security Agreement between Pacific Western Bank (n/k/a PacWest Bancorp) and the Registrant, dated March 9, 2018, as amended on September 30, 2019, January 22, 2020 and December 30, 2020.	S-1/A	333-257794	10.1	07/26/2021	
10.15	Fourth Amendment to Loan and Security Agreement, dated December 20, 2021.	8-K	001-40657	10.1	12/21/2021	
10.16	Fifth Amendment to Loan and Security Agreement, dated September 22, 2023.	8-K	001-40657	10.1	09/22/2023	
10.17†	License Agreement between Flagship Pioneering Innovations V, Inc. and the Registrant, dated March 12, 2019.	S-1	333-257794	10.1	07/09/2021	
10.18†	Letter Agreement re License Agreement between Flagship Pioneering Innovations V, Inc. and the Registrant dated December 31, 2023 relating to the License Agreement dated March 12, 2019					*
10.19†	Exclusive License Agreement between the Whitehead Institute for Biomedical Research and the Registrant, dated May 22, 2019.	S-1	333-257794	10.1	07/09/2021	
10.20†	Waiver, Confirmation and Agreement Regarding Research Collaboration effective December 31, 2023, between Whitehead Institute for Biomedical Research and the Registrant, relating to Exclusive License Agreement, dated May 22, 2019.					*
10.21†	Co-Exclusive License Agreement between the Whitehead Institute for Biomedical Research and the Registrant, dated May 22, 2019.	S-1	333-257794	10.1	07/09/2021	
10.22†	Waiver, Confirmation and Agreement Regarding Research Collaboration effective December 31, 2023, between Whitehead Institute for Biomedical Research and the Registrant, relating to Co-Exclusive License Agreement, dated May 22, 2019.					*
10.23†	Development and Option Agreement between Acuitas Therapeutics, Inc. and the Registrant, dated October 5, 2020, as amended.	S-1	333-257794	10.2	07/09/2021	
10.24†	Non-Exclusive License Agreement between Acuitas Therapeutics, Inc. and the Registrant, dated March 22, 2021.	S-1	333-257794	10.2	07/09/2021	
10.25†	Collaboration and License Agreement between Nitto Denko Corporation and the Registrant, dated October 12, 2022.	10-K	001-40657	10.20	03/01/2023	
10.26	Lease Agreement between BMR-325 Vassar Street LLC and the Registrant, dated November 30, 2017.	S-1/A	333-257794	10.1	07/26/2021	

10.27	Lease Agreement between Omega Therapeutics, Inc. and ARE-MA Region No, 94, LLC.	10-K	001-40657	10.1	03/10/2022	
10.28	First Amendment to Lease between Omega Therapeutics, Inc. and ARE-MA Region No. 94, LLC, dated May 3, 2023	10-Q	001-40657	10.1	08/03/2023	
10.29	Amendment to Shared Space Agreement between Omega Therapeutics, Inc. and Senda Biosciences, Inc., dated January 31, 2022.	10-K	001-40657	10.1	03/10/2022	
10.30	Shared Space Agreement, dated as of July 12, 2023, by and between Omega Therapeutics, Inc. and Metaphor Biotechnologies, Inc.	8-K	001-40657	10.1	07/13/2023	
10.31	Shared Space Agreement, dated as of July 11, 2023, by and between Omega Therapeutics, Inc. and Apriori Bio, Inc.	8-K	001-40657	10.2	07/13/2023	
10.32	Shared Space Agreement, dated as of July 12, 2023, by and between Omega Therapeutics, Inc. and Flagship Labs 89, Inc.	8-K	001-40657	10.3	07/13/2023	
10.33†	Research Collaboration Agreement with Novo Nordisk A/S, Pioneering Medicines 08, Inc., Omega Therapeutics, Inc. and the other parties thereto, dated as of December 31, 2023					*
10.34	Open Market Sale Agreement dated as of August 3, 2023 between Omega Therapeutics, Inc. and Jefferies LLC	8-K	001-40657	10.1	08/03/2023	
10.35	Securities Purchase Agreement, dated as of February 22, 2023, by and between Omega Therapeutics, Inc. and the purchasers named therein	8-K	001-40657	10.1	02/02/2023	
21.1	Subsidiaries of the Registrant.	10-K	001-40657	21.1	03/10/2022	
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.					*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.					**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					**
97	Policy Relating to Recovery of Erroneously Awarded Compensation					*
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 28, 2024

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.

Name	Title	Date
/s/ Mahesh Karande **Mahesh Karande**	President, Chief Executive Officer and Director (principal executive officer)	March 28, 2024
/s/ Joshua Reed **Joshua Reed**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 28, 2024
/s/ Christian S. Schade **Christian S. Schade**	Chairman of the Board of Directors	March 28, 2024
/s/ Rainer Boehm **Rainer Boehm**	Director	March 28, 2024
/s/ Luke M. Beshar **Luke M. Beshar**	Director	March 28, 2024
/s/ Elliott M. Levy **Elliott M. Levy, M.D.**	Director	March 28, 2024
/s/ John Mendlein **John Mendlein, Ph.D., J.D.**	Director	March 28, 2024
/s/ Mary T. Szela **Mary T. Szela**	Director	March 28, 2024
/s/ Michelle C. Werner **Michelle C. Werner**	Director	March 28, 2024
/s/ Richard A. Young **Richard A. Young, Ph.D.**	Director	March 28, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 its subsidiary (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows, for each of the two years in the period ended December 31, 2023 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and the need to raise additional capital to finance its future operations raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 28, 2024
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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 68,443	$ 70,615
Marketable securities	4,986	54,063
Accounts receivable, due from related party	1,006	618
Accounts receivable	5,125	—
Prepaid expenses and other current assets	10,324	12,294
Total current assets	89,884	137,590
Property and equipment, net	5,311	4,195
Operating lease right-of-use assets, net	108,736	3,668
Restricted cash	341	341
Other assets	94	204
Total assets	$ 204,366	$ 145,998
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,620	$ 3,107
Accrued expenses	7,914	13,841
Other current liabilities	1,972	159
Lease liabilities, current	11,300	1,524
Long-term debt, current portion	4,000	3,333
Total current liabilities	26,806	21,964
Lease liabilities, non-current	98,243	1,120
Long-term debt, net	14,885	16,603
Other liabilities	6,416	340
Total liabilities	146,350	40,027
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of December 31, 2023 and December 31, 2022; no shares issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 55,144,982 and 48,072,517 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	55	48
Additional paid-in capital	392,609	343,608
Accumulated other comprehensive loss	(14)	(479)
Accumulated deficit	(334,634)	(237,206)
Total stockholders' equity	58,016	105,971
Total liabilities and stockholders' equity	$ 204,366	$ 145,998

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)

	Year Ended December 31,	
	2023	2022
Collaboration revenue from related party	$ 3,094	$ 2,073
Operating expenses:		
Research and development	77,169	81,167
General and administrative	26,186	23,672
Total operating expenses	103,355	104,839
Loss from operations	(100,261)	(102,766)
Other income (expense), net:		
Interest income, net	2,810	222
Other income (expense), net	23	(157)
Total other income, net	2,833	65
Net loss	$ (97,428)	$ (102,701)
Net loss per common stock attributable to common stockholders, basic and diluted	$ (1.80)	$ (2.14)
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	54,010,996	47,880,819
Comprehensive loss:		
Net loss	$ (97,428)	$ (102,701)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	465	(417)
Comprehensive loss	$ (96,963)	$ (103,118)

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

Omega Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	COMMON STOCK					
	SHARES	PAR VALUE	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE GAIN (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
As of January 1, 2022	47,793,469	$ 48	$ 335,147	$ (62)	$ (134,505)	$ 200,628
Issuance of common stock for options exercised	279,048	—	708	—	—	708
Other comprehensive loss	—	—	—	(417)	—	(417)
Stock-based compensation	—	—	7,753	—	—	7,753
Net loss	—	—	—	—	(102,701)	(102,701)
As of December 31, 2022	48,072,517	$ 48	$ 343,608	$ (479)	$ (237,206)	$ 105,971
Issuance of common stock for registered direct offering, net of issuance costs	6,920,415	7	39,720	—	—	39,727
Issuance of common stock for options exercised	152,050	—	488	—	—	488
Other comprehensive gain	—	—	—	465	—	465
Stock-based compensation	—	—	8,793	—	—	8,793
Net loss	—	—	—	—	(97,428)	(97,428)
As of December 31, 2023	55,144,982	$ 55	$ 392,609	$ (14)	$ (334,634)	$ 58,016

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,	
	2023	2022
Operating activities		
Net loss	$ (97,428)	$ (102,701)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,568	1,564
Amortization of debt issuance costs and debt discount	53	67
Amortization of operating lease right-of-use assets	5,203	3,626
Accretion of discounts on marketable securities	(192)	1,045
Change in fair value of success fee obligation	92	13
Gain on disposal of fixed assets	(233)	—
Stock-based compensation expense	8,793	7,753
Changes in operating assets and liabilities:		
Accounts receivable, due from related party	(388)	(362)
Accounts receivable	(5,125)	
Prepaid expenses and other current assets	1,418	(8,592)
Other assets	111	(3,763)
Accounts payable	(1,487)	985
Accrued expenses and other current liabilities	(5,558)	3,233
Other liabilities	1,663	(1,383)
Net cash used in operating activities	(91,510)	(98,515)
Investing activities		
Purchases of property and equipment	(2,869)	(1,380)
Proceeds from sale of property and equipment	650	
Purchases of marketable securities	(19,768)	(57,415)
Proceeds from maturities of marketable securities	69,502	40,735
Net cash provided by (used in) investing activities	47,515	(18,060)
Financing activities		
Proceeds from equity offering	40,000	—
Payments of equity offering costs	(273)	—
Proceeds from lease financing	2,623	—
Repayment of debt	(1,000)	—
Payments of financing fees	(15)	—
Proceeds from issuance of common stock under equity incentive plans	488	708
Net cash provided by financing activities	41,823	708
Net change in cash, cash equivalents and restricted cash	(2,172)	(115,867)
Cash, cash equivalents and restricted cash—beginning of period	70,956	186,823
Cash, cash equivalents and restricted cash—end of period	$ 68,784	$ 70,956
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 68,443	$ 70,615
Restricted cash	341	341
Cash, cash equivalents and restricted cash	$ 68,784	$ 70,956
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,723	$ 1,263
Supplemental disclosure of noncash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 438	$ 13

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 clinical-stage biotechnology company pioneering the development of a new class of programmable epigenomic mRNA medicines by leveraging its 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 its 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 clinical-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, risks related to clinical development 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. In February 2023, the Company completed a registered direct offering of common stock pursuant to which it issued and sold 6,920,415 shares of its common stock at a purchase price of $5.78 per share and secured approximately $39.7 million in net proceeds after deducting offering expenses.

The Company expects that its cash, cash equivalents and marketable securities of $73.4 million at December 31, 2023, will enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2025. The Company has had recurring losses since inception and incurred a loss of $97.4 million during the year ended December 31, 2023. Net cash used in operations for the year ended December 31, 2023 was $91.5 million. The Company expects to continue to generate operating losses and use cash in operations for the foreseeable future. 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. Volatility in the capital markets and general economic conditions in the United States may be a significant obstacle to raising the required funds and, as a result, the Company may be unable to secure the necessary funding on acceptable terms. This raises substantial doubt about the Company's ability to continue as a going concern.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Significant Risks and Uncertainties Related to Macroeconomic Conditions

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including, for example, severely diminished liquidity and credit availability, rising interest and inflation rates, crises involving banking and financial institutions, declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. In addition, unstable market and economic conditions and further disruption created by pandemics or international political unrest, war and terrorism may have serious adverse consequences on our business, financial condition and results of operations.

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.

Reclassification

The Company reclassified the related party expenses in the prior year to research and development and general and administrative expenses in the consolidated statements of operations and comprehensive loss to conform to the current year's presentation.

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 value of the success fee obligation, the incremental borrowing rate used in the calculation of lease liabilities, research and development expenses, certain judgments regarding revenue recognition 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, 2023 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 a 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, 2023 and 2022, 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:

Asset category	Estimated useful life
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 and clinical 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.

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.

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 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. There were no deferred offering costs as of December 31, 2023 and 2022.

Impairment of long-lived assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment and operating lease right-of-use assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment losses recognized during the years ended December 31, 2023 and 2022.

Leases

The Company has real estate leases for its corporate offices and lab space located in Cambridge, Massachusetts. It determines if an arrangement contains a lease at contract inception. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. Lease payments are typically fixed and escalate over time. Variable payments relate to the Company's usage or share of the lessor's operating costs associated with the underlying asset and are recognized as incurred. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that it will exercise that option. The Company uses its incremental borrowing rate to calculate the lease liability when the implicit rate is not readily determinable. Lease expense is recognized on a straight-line basis over the lease term.

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.

Revenue recognition

Revenue recognized through December 31, 2023 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 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.

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, 2023 and 2022, 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

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.

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, 2023 and 2022.

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.

Recent accounting pronouncements adopted

On January 1, 2023, the Company adopted Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the Financial Accounting Standards Board ("FASB") issued clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*. The guidance is effective for fiscal years beginning after December 15, 2022. The adoption of the standard was immaterial to the accompanying consolidated financial statements.

Recent accounting pronouncements not yet adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)*, *Improvements to Reportable Segment Disclosures*. The new standard requires enhanced disclosures about segment information and significant segment expenses. It does not change how a public entity identifies its operating segments. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The new standard should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact on its consolidated financial statements.

In December 2023, the FASB issued 2023-09, *Income Taxes (Topic 740), Improvements to Income Tax Disclosures*. The new standard requires public business entities to disclose information about income taxes paid, specific categories in the rate reconciliation, and additional information for reconciling items that meet a quantitative threshold. The guidance should be applied on a prospective basis. For public business entities, ASU 2023-08 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. For all other entities, the standard is effective for annual periods beginning after December 15, 2025. The Company is currently evaluating the impact on its consolidated financial statements.

3. Marketable Securities

The following table summarizes the Company's marketable securities (in thousands):

	December 31, 2023		
	Amortized cost	Gross unrealized losses	Fair value
Corporate debt securities	$ 5,000	$ (14)	$ 4,986

	December 31, 2022		
	Amortized cost	Gross unrealized losses	Fair value
Corporate debt securities	$ 54,542	$ (479)	$ 54,063

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. At December 31, 2023, 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, 2023 and, as a result, the Company did not reclassify any amounts out of accumulated other comprehensive loss during the year.

As of December 31, 2023, 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, 2023.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2023	2022
Clinical development	$ 5,168	$ 5,232
Research and development	1,609	2,072
Facilities	1,242	1,857
Other receivables	855	1,180
Insurance	716	1,020
Software	303	157
Other	431	776
Prepaid expenses and other current assets	$ 10,324	$ 12,294

5. Property and Equipment, Net

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

	December 31,	
	2023	2022
Lab equipment	$ 6,633	$ 6,121
Furniture and fixtures	1,636	1,093
Leasehold improvements	1,290	1,378
Computer equipment	1,226	190
Construction in process	588	827
Total property and equipment	11,373	9,609
Less accumulated depreciation	(6,062)	(5,414)
Property and equipment, net	$ 5,311	$ 4,195

Depreciation expense for each of the years ended December 31, 2023 and 2022 was $1.6 million, respectively.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2023	2022
Employee related expenses	$ 4,482	$ 4,368
Research costs	1,395	3,876
Professional and consulting fees	716	743
Manufacturing costs	547	4,303
Interest	147	122
Other	627	429
Total	$ 7,914	$ 13,841

7. Term Loan

On March 9, 2018, the Company entered into the Loan Agreement with Pacific Western Bank (“PWB”) to initially borrow $8.0 million, which was further amended on September 30, 2019 (the "First Amendment"), January 22, 2020 (the "Second Amendment"), December 30, 2020 (the “Third Amendment”), and December 20, 2021 (the "Fourth Amendment").

On September 22, 2023, the Company entered into another amendment to the Loan Agreement (the "Fifth Amendment"), in which PWB extended the maturity date of the loan to September 30, 2027, subject to further extension to September 30, 2028 upon receipt by the Company on or before December 31, 2024 of at least $50.0

million of cash proceeds from the sale of its equity securities and/or non-refundable upfront strategic partnership proceeds. Repayment of the loan began on September 30, 2023, with monthly principal payments of $0.3 million plus interest, along with a closing payment of $4.0 million on September 30, 2027 if the maturity date is not extended to September 30, 2028. Interest will continue to be determined at a floating annual rate equal to the greater of (i) 0.50% above the prime rate then in effect and (ii) 5.50%. The Company incurred $15 thousand of debt issuance costs, which was recorded as a direct reduction against the additional term loan and will be amortized over the life of the associated term loan as a component of interest expense using the effective interest method. Under the terms of the Fifth Amendment, the Company is required to pay a success fee of $0.1 million pursuant to the Fifth Amendment, in addition to the $0.2 million success fee obligation pursuant to the Fourth Amendment. The success fees are contingent on achieving specified liquidity events. The Company determined that the success fee obligation represented a freestanding financial instrument, and it was classified as a liability on the Company's consolidated balance sheet 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.

In addition, pursuant to the Fifth Amendment, the Company agreed to maintain with PWB, at all times, a balance of at least $5.0 million of unrestricted cash, subject to termination upon the Company's prepayment of outstanding loans in an aggregate amount of at least $5.0 million or if the principal balance of the loans is less than $10.0 million.

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, 2023, $4.0 million of the net carrying amount of the term loan was classified as short-term and $14.9 million was classified as long-term based on the repayment start date. The Company's outstanding term loan balance was comprised of the following (in thousands):

	December 31,	
	2023	2022
Principal	$ 19,000	$ 20,000
Unamortized debt discount	(115)	(64)
Net carrying amount	$ 18,885	$ 19,936

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 9.26% for the period from the date of issuance through December 31, 2023. The following table sets forth total interest expense recognized related to the term loan (in thousands):

	Year Ended December 31,	
	2023	2022
Contractual interest expense	$ 1,748	$ 1,229
Amortization of debt issuance costs and debt discount	53	67
Total interest expense	$ 1,801	$ 1,296

At December 31, 2023 and December 31, 2022, accrued interest on the term loan was $147 thousand and $121 thousand, respectively.

The Company is required to repay the following principal amounts in connection with its term loan (in thousands):

2024	$ 4,000
2025	4,000
2026	4,000
2027	7,000
Total	$ 19,000

8. Fair Value of Financial Instruments

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, 2023 and 2022, 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 success fee obligation associated with the Loan Agreement, as amended, contains 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 success fee obligation is measured at its fair value on a recurring basis using unobservable inputs.

The fair value of the Company's financial instruments is summarized in the table below (in thousands):

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial Assets				
Money market funds	$ 10,402	$ —	$ —	$ 10,402
Corporate Debt Securities	—	4,986	—	4,986
Total	$ 10,402	$ 4,986	$ —	$ 15,388
Financial Liabilities				
Success fee obligations	$ —	$ —	$ 300	$ 300

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial Assets				
Money market funds	$ 25,776	$ —	$ —	$ 25,776
Corporate Debt Securities	—	54,063	—	54,063
Total	$ 25,776	$ 54,063	$ —	$ 79,839
Financial Liabilities				
Success fee obligation	$ —	$ —	$ 118	$ 118

In accordance with the Fourth and Fifth Amendments of the Loan Agreement with PWB, the Company will be required to pay success fees totaling $0.3 million upon the achievement of certain liquidity events; accordingly, the related obligation is recorded as current liabilities on the consolidated balance sheets as it is deemed more probable than not by the Company to be settled in less than one year. 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 the discount rate. The fair value of the success fee obligation is 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 of December 31, 2023, the Company determined it was 100% probable of achieving the specified liquidity events and therefore accrued the full amount of the success fee obligations. The following reflects the significant quantitative inputs used to determine the valuation of the success fee obligation for the years ended December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Discount rate	9.0 %	8.0 %
Expected timing of achieving liquidity events (years)	1.0	0.3 - 1.3
Probability of achieving liquidity events	100%	75% -25%

The following table provides a roll-forward of the fair values of the Company's success fee obligation for which fair value is determined by Level 3 inputs (in thousands):

	Success fee obligation from the Fourth Amendment	Success fee obligation from the Fifth Amendment
Fair value at January 1, 2023	$ 118	$ —
Initial fair value of success fee obligation	—	90
Change in fair value	82	10
Fair value at December 31, 2023	$ 200	$ 100

9. Commitments and contingencies

Leases

The Company has the following operating leases for its corporate offices and lab space located in Cambridge, Massachusetts.

325 Vassar Street

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. In 2019 and 2020, the Company entered into sublease agreements with two related parties to sublease this office and laboratory space. Refer to Note 16, *Related party transactions*, for further details.

20 Acorn Park Drive

On July 13, 2020, the Company entered into a Shared Space Arrangement (the Arrangement) with Sail Biomedicines, Inc., (“Sail Bio”, also formerly known as Senda Biosciences, Inc. and Kintai Therapeutics, Inc. prior to its merger with LARONDE, Inc.) to share one-third of Sail Bio's 69,867 square feet of leased space at 20 Acorn Park Drive, Cambridge, Massachusetts. Sail Bio is a related party as it is an affiliate of Flagship Pioneering (“Flagship”). The Arrangement commenced on August 1, 2020, and was set to expire on 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. In January 2022, the Company entered into an amendment to the Arrangement with Sail Bio to exercise the option to renew the lease through July 2023. The Company also modified certain provisions related to the extension term. Refer to Note 16, *Related party transactions*, for further details.

140 First Street (formerly known as One Charles Park)

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 140 First Street, Cambridge, Massachusetts, 02142. The lease includes two phases. Phase 1 includes approximately 78,380 rentable square feet. Phase 2 includes 10,866 rentable square feet in a separate suite. In accordance with the lease agreement, the Company paid $0.8 million upon the execution of the lease, which has offset the first month's rent. Phase 1 of the lease commenced in May 2023, and Phase 2 commenced in August 2023.

On May 3, 2023, the Company entered into a first amendment to the lease to, among other things, delay the delivery date of part of the premises, increase the initial base rent by $1.00 per rentable square foot per year, and change the address. The operating lease commenced on May 1, 2023 for the fifth floor premises and August 1, 2023 for the first floor premises for accounting purposes. The lease term for each of the floor premises is fifteen years from the respective commencement date, subject to certain extension rights. The base rent for the leased space is $116.00 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 full payment of rent under the lease. The operating lease includes a tenant improvement allowance of $300 per rentable square foot that is incorporated into the base rent payments, as well as an additional improvement allowance that is required to be repaid to the landlord as additional monthly rent over the lease term at an interest rate of 8%.

On July 11, 2023, the Company entered into a Shared Space Arrangement with Apriori Bio, Inc. (“Apriori”), and on July 12, 2023, the Company entered into two Shared Space Arrangements with Metaphore Biotechnologies, Inc. (“Metaphore”) and Flagship Labs 89, Inc. (“FL Labs” and, together with Metaphore and Apriori, the “Subtenants”), pursuant to which the Company agreed to sublease an aggregate of approximately 22,500 rentable square feet of office and laboratory space located at 140 First Street, Cambridge, Massachusetts, 02141 (the “Premises”). The Company leases an aggregate of approximately 89,246 rentable square feet of office and laboratory space located at the Premises pursuant to its lease with ARE-MA Region No. 94, LLC. Metaphore, Apriori and FL Labs are affiliates of Flagship Pioneering, a significant stockholder of the Company. The term of the Sublease with Metaphore and FL Labs has commenced in August, 2023 and will end in August, 2025, and the term of the Sublease with Apriori began in September, 2023 and will end in September, 2025. The Subleases provide that the Subtenants will pay to the Company a monthly license fee that is a proportionate share of the actual base rent, operating expenses and other costs for the use and occupancy of the subleased portion of the Premises charged by the Landlord under the Lease and paid by the Company. Such proportionate share will be 12.0%, 8.4% and 8.4% for Metaphore, Apriori and Labs, respectively. The total commitment for the Subtenants' share of the base rent over the term of the Subleases is $5.2 million. The Company may terminate each Sublease and require the applicable Subtenant to immediately vacate the Premises if such Subtenant causes a default under the Lease, is in default of any provision in the applicable Sublease or acts in a manner deemed by the Company, in its sole discretion, as dangerous or threatening. The Subleases contain customary covenants, obligations and indemnities in favor of either party. For the year ended December 31, 2023, the Company received rental income of $1.4 million, which was recorded as a reduction of research and development expense and general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss.

As of December 31, 2023, operating lease right-of-use assets, net were $108.7 million, which were recorded separately on the Company’s consolidated balance sheet. The corresponding operating lease liabilities were $109.5 million as of December 31, 2023, of which $11.3 million were recorded in current liabilities and $98.2 million were recorded in long-term liabilities on the Company’s consolidated balance sheet.

The right-of-use assets represent the Company’s right to use an underlying asset during the lease term and the related lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Both the right-of-use assets and the corresponding liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. As the Company’s leases do not provide an implicit rate, the Company estimated the incremental borrowing rate based on the interest rate from the amended Term Loan, which was fully collateralized, as well as a term matched secured market rate.

The following table summarizes the components of lease expense for the years ended December 31, 2023 and 2022 (in thousands).

	Year Ended	
	December 31, 2023	December 31, 2022
Operating lease expense	$ 11,624	$ 3,820
Variable lease expense	2,819	1,357
Total lease expense	$ 14,443	$ 5,177

Variable lease expense generally includes common area maintenance, utilities and property taxes. For the year ended December 31, 2023, $11.3 million of lease expense was recorded within research and development expenses and $3.1 million was recorded within general and administrative expenses in the consolidated statement of operations and comprehensive loss. For the year ended December 31, 2022, $3.9 million of lease expense was recorded within research and development expenses and $1.2 million was recorded within general and administrative expenses in the consolidated statement of operations and comprehensive loss.

The weighted average remaining lease term and discount rate related to the Company's leases were as follows:

	As of	
	December 31, 2023	December 31, 2022
Weighted average remaining lease term (years)	14.5	1.8
Weighted average discount rate	8.9%	5.5%

Supplemental cash flow information relating to the Company's leases for the years ended December 31, 2023 and December 31, 2022 were as follows (in thousands):

	Year Ended	
	December 31, 2023	December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities	$ 8,542	$ 2,637
Operating lease assets obtained in exchange for lease liabilities	$ 110,424	$ 4,393

As of December 31, 2023, the estimated minimum lease payments for 140 First Street and 325 Vassar for each of the years ending December 31 were as follows (in thousands):

2024	$ 11,781
2025	11,887
2026	12,213
2027	12,549
2028	12,895
Thereafter	139,504
Total minimum lease payments	200,829
Less: Imputed interest	(91,286)
Present value of operating lease liabilities	$ 109,543

Thermo Furniture Sale-Leaseback

In December 2023, the Company entered into a sale-leaseback arrangement with Thermo Fisher Financial Services, Inc. to provide $2.6 million in cash proceeds for previously acquired furniture and equipment. The term of the leaseback is 5 years, with an option to purchase the assets for $1 at the end of the term. The Company concluded the leaseback would be classified as a financing lease. Therefore, the transaction was deemed a failed sale-leaseback and was accounted for as a financing arrangement. The Company will make monthly payments of $53 thousand over the term of the lease. As of December 31, 2023, $0.4 million of the financing obligation is included in current liabilities and $2.2 million is included in long-term liabilities on the Company's consolidated balance sheet. The assets continue to be depreciated over their useful lives, and payments are allocated between interest expense and repayment of the financing liability.

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 and regulatory milestones. In addition, the Company is required to pay to WIBR annual fees of less than $0.1 million for each sublicense agreement.

For the years ended December 31, 2023 and 2022, the Company recognized expenses of $0.2 million and less than $0.2 million, respectively, for license maintenance fees and milestone payments. There was no outstanding payment due to WIBR as of December 31, 2023 and December 31, 2022.

The annual maintenance fees 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. Lastly, the royalty payments and the sublicense non-royalty payments are contingent upon sales of licensed 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., EC 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 products, 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 years ended December 31, 2023 and 2022, the Company recorded an aggregate of $0.4 million and $1.9 million of research and development expenses, respectively, consisting of technology access fees, target reservation and maintenance fees, the costs of services performed by Acuitas, material costs and 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 in March 2021. 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. For the year ended December 31, 2022, an annual maintenance fee of $0.8 million has been recorded as research and development expense. There were no milestones triggered, and no expense was recorded related to them for the years ended December 31, 2023. Lastly, the royalty payment is contingent upon sales of licensed products under the Acuitas License Agreement. As such, 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.

Nitto Denko Corporation

On October 12, 2022, the Company entered into a Collaboration and License Agreement (the "Nitto Agreement") with Nitto Denko Corporation ("Nitto"), pursuant to which, among other things, Nitto granted the Company an exclusive, worldwide, royalty-bearing, fully transferable and fully sublicensable license under all intellectual property owned or controlled by Nitto relating to its lipid nanoparticle delivery technology.

Under the terms of the Nitto Agreement, the Company has made an upfront cash payment of $1.0 million, and developmental milestone payments of $1.0 million to Nitto in 2022. Both payments have been recorded as research and development expenses. The Company is also required to make up to $83.0 million in future payments to Nitto based upon the achievement of specified development, regulatory and sales milestones. The Company is also obligated to pay to Nitto tiered, single-digit percentage royalties on a country-by-country basis based on net sales of the licensed product, subject to reduction in specified circumstances. As such, when these expenses are considered probable and estimable, the Company will accrue expense for the amount the Company is obligated.

During the year ended December 31, 2023, the Company recorded an aggregate of $0.9 million of research and development expenses consisting of material costs, costs of services performed by Nitto, and reimbursable costs.

11. Collaboration Agreements

PMCo

In November 2021, the Company entered into a five-year collaboration agreement with PM (CF) Explorations, Inc. ("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 performs 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 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 total transaction price at December 31, 2023 was determined to be $7.9 million based on the current estimated required efforts to fulfill the performance obligation. This total includes an increase of $1.9 million in the fourth quarter of 2022, and an increase of $2.4 million in the third quarter of 2023, and an increase of $0.1 million in the fourth quarter of 2023, all of which were agreed upon with PMCo. As of December 31, 2023, the remaining transaction price was estimated to be $2.7 million, which is expected to be recognized as revenue through 2024.

The Company recognized funded research and collaboration revenue of $3.1 million and $2.1 million in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2023 and 2022, respectively. Costs incurred associated with this collaboration agreement were recorded as research and development expenses.

Pursuant to the agreement, the Company is 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, 2023, the Company determined that the proceeds from such transaction was not probable of recognition.

Nitto Denko Corporation

On October 12, 2022, the Company entered into a Collaboration and License Agreement with Nitto, pursuant to which, among other things, Nitto granted the Company an exclusive, worldwide, royalty-bearing, fully transferable and fully sublicensable license under all intellectual property owned or controlled by Nitto relating to its lipid nanoparticle delivery technology. See further discussion in Note 10, *License Agreements*.

Novo Nordisk

On December 31, 2023, the Company entered into a Research Collaboration Agreement with Novo Nordisk A/S ("Novo Nordisk") and Pioneering Medicines 08, Inc., an affiliate of Flagship (and with respect to certain provisions set forth in the agreement, Pioneering Medicines (NN), LLC and PM (NN) Explorations, Inc.). Under the terms of the agreement, the Company granted to Novo Nordisk an exclusive, royalty-bearing, transferable license, with the right to grant sublicenses through multiple tiers, for certain of its intellectual property to conduct research and development activities under an agreed-upon research and development plan relating to a product candidate, or program target, for the prevention, treatment or control of a cardiometabolic disease, including diabetes.

In January 2024, the Company received an upfront nonrefundable payment of $5.1 million from Novo Nordisk and expects to receive approximately $21.6 million in cost reimbursement through 2027 to fund the related research and development activities. The research plan funding may be adjusted upon mutual written agreement from all the parties. The Company is also eligible to receive development and commercial milestone payments, as well as tiered royalties on annual net sales of a licensed product. The term of the agreement expires at the end of the royalty term, which is the later of the 10th anniversary of the first commercial sale, the expiration of the last-to-expire payment claim, or expiration of regulatory exclusivity. Upon the expiration of the royalty term for a given licensed product in a given country in the territory, the licenses granted to Novo Nordisk pursuant to the agreement under the Omega licensed intellectual property survive and become perpetual, irrevocable, fully paid-up and royalty free with respect to such licensed product in such country.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Novo Nordisk, is a customer. The Company determined that the research activities and the

exclusive license granted under the collaboration agreement is considered as a single combined performance obligation as they are incapable of being distinct. The Company will recognize revenue related to the single performance obligation over time using the input method. Under the input method, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation, which the Company believes best measures its progress towards satisfying the combined performance obligation. A cost-based input method of revenue recognition requires management to make estimates of costs to complete performance obligation. In making such estimates, judgment is required to evaluate assumptions related to cost estimates.

As of December 31, 2023, the total transaction price was determined to be $26.7 million based on the upfront nonrefundable payment and estimated required research and development efforts. The total transaction price, including the $5.1 million nonrefundable upfront payment, is expected to be recognized as revenue beginning in 2024 through 2027. The Company will assess the probability of achieving the milestones and include them in the transaction price when they are deemed probable. Royalties will be recognized when the subsequent sales occur based on the sales or usage-based royalty exception. Costs incurred associated with this research collaboration agreement are recorded as research and development expenses.

12. Preferred and Common Stock

In 2021, 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.

In February 2023, the Company completed a registered direct offering of common stock pursuant to which it issued and sold 6,920,415 shares of its common stock at a purchase price of $5.78 per share and secured approximately $39.7 million in net proceeds after deducting estimated offering expenses of $0.3 million.

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, 2023, the Company has reserved an aggregate of 8,780,737 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 3,902,063 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.

13. Equity Incentive Plans

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, 2023, there were no shares available for future grants under the 2017 Plan and a total of 3,902,063 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, 2031, 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, 2023, there were 2,581,038 shares available for future grants under the 2021 Plan, and a total of 4,878,674 shares of the Company's common stock were subject to outstanding stock options issued under the 2021 Plan.

The Company recorded stock-based compensation expense as 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,	
	2023	2022
Research and development	$ 4,269	$ 4,026
General and administrative	4,524	3,727
Total stock-based compensation expense	$ 8,793	$ 7,753

Stock Options

The assumptions used in the Black-Scholes option-pricing model for stock options granted were as follows:

	Year ended December 31,	
	2023	2022
Expected volatility	74.65% - 77.06%	76.09% - 77.62%
Weighted-average risk-free interest rate	4.16%	2.69%
Expected dividend yield	0.00%	0.00%
Weighted-average expected term (in years)	6.08	6.11

A summary of option activity under the Company's equity incentive plans during the year ended December 31, 2023 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, 2023	8,438,573	$ 6.00	8.40	$ 12,976
Granted	1,586,002	5.74		
Exercised	(152,050)	3.21		
Forfeited	(964,787)	7.96		
Expired	(127,001)	12.73		
Outstanding as of December 31, 2023	8,780,737	5.69	7.52	5,033
Vested and expected to vest as of December 31, 2023	8,780,737	5.69	7.52	5,033
Exercisable as of December 31, 2023	4,837,051	$ 4.79	6.71	$ 4,599

[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, 2023.

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2023 and 2022 was $3.97 and $5.08, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2023 and 2022 was $0.7 million and $1.0 million, respectively.

As of December 31, 2023, there was $16.5 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.0 years.

2021 Employee Stock Purchase Plan

The Company's board of directors adopted, and the Company's stockholders approved, the Employee Stock Purchase Plan (the "2021 ESPP") in July 2021. The purpose of the 2021 ESPP is to provide eligible employees with an opportunity to purchase shares of the Company's common stock through accumulated contributions. The 2021 ESPP permits participants to purchase shares of common stock through contributions (generally in the form of payroll deductions) of up to an amount of their eligible compensation determined by the administrator. Subject to certain other limitations or unless otherwise determined by the administrator, a participant may purchase a maximum of 100,000 shares of common stock during an offering period. The offering periods under the 2021 ESPP will begin on such date as determined by the administrator and not exceed 27 months. Amounts deducted and accumulated by the participant are used to purchase shares of common stock on each exercise date. The purchase price of the shares will be determined by the administrator but in no event will be less than 85% of the lower of the fair market value of common stock on the enrollment date or on the exercise date. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of common stock, provided that they give notice of such withdrawal within the time period required by the administrator. Participation ends automatically upon termination of employment with the Company.

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.

As of December 31, 2023, the Company had not consummated an offering period under the 2021 ESPP. As of December 31, 2023, the Company had 1,438,649 shares of common stock available for issuance under the 2021 ESPP.

14. 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,	
	2023	2022
Numerator:		
Net loss attributable to common stockholders	$ (97,428)	$ (102,701)
Denominator:		
Weighted average number of common stock, basic and diluted	54,010,996	47,880,819
Net loss per common stock attributable to common stockholders, basic and diluted	$ (1.80)	$ (2.14)

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:

	As of December 31,	
	2023	2022
Outstanding options to purchase common stock	8,780,737	8,438,573

15. 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,	
	2023	2022
U.S. federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	6.6	7.1
Research and development tax credits	4.7	4.3
Nondeductible/ nontaxable permanent items	(0.9)	(0.5)
Change in valuation allowance	(31.4)	(32.0)
Other	0.0	0.1
Effective income tax rate	0.0%	0.0%

The components of the Company's deferred taxes are as follows (in thousands):

	Year ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 50,762	$ 40,157
Research and development credit carryforwards	16,309	11,013
Accrued expenses	1,154	1,098
Stock-based compensation	3,329	1,726
Intangibles	120	136
IRC 174 R&D capitalization	32,505	20,024
ASC 842 lease liability	30,198	722
Unrealized gain/loss	—	325
Total deferred tax assets	134,377	75,201
Less: valuation allowance	(104,630)	(74,005)
Deferred tax assets, net	29,747	1,196
Deferred tax liabilities:		
Depreciation	(12)	(194)
Right of use asset	(29,706)	(1,002)
Unrealized gain/loss	(29)	—
Total deferred tax liabilities	(29,747)	(1,196)
Net deferred taxes	$ —	$ —

The Company had no income tax expense due to the operating loss incurred for the years ended December 31, 2023 and 2022. 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, 2023 and 2022. The valuation allowance increased by $30.6 million in 2023, due to the increase in deferred tax assets, primarily resulting from the net operating loss carryforwards, research and development tax credits, IRC 174 R&D capitalization, 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, 2023, the Company had $187.4 million of federal and $180.4 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 $187.4 million federal net operating loss carryforwards, $181.9 million of net operating loss generated from 2018 to 2023 will not expire. Additionally, as of December 31, 2023, the Company had $12.4 million of federal and $4.9 million of Massachusetts tax credits that expire starting in 2036 and 2031, respectively.

As of December 31, 2023 and 2022, 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. All tax years 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.

16. Related Party Transactions

For the year ended December 31, 2023, related party transactions consisted primarily of rent payments and reimbursable expenses, offset by sublease income received from related parties.

The majority ownership of the Company is held by Flagship, in which it holds shares representing approximately 53% of the Company's outstanding voting stock as of December 31, 2023. Flagship historically provided management services to the Company, and the Company reimburses Flagship for certain expenses, including insurance and benefits, and related fees, and software licenses incurred on the Company's behalf. For the years ended December 31, 2023 and 2022, the Company incurred $0.2 million and $1.7 million, respectively, primarily for reimbursable expenses. These expenses are recorded as general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2023 and 2022, there was an immaterial amount of outstanding payments due to Flagship.

In July 2023 the Company entered into three Shared Space Agreements with related parties Metaphore Biotechnologies, Inc., Apriori Bio, Inc., and Flagship Labs 89, Inc. These companies are affiliates of Flagship Pioneering, a significant stockholder of the Company. Pursuant to the agreements, the Company agreed to sublease an aggregate of approximately 22,500 rentable square feet of office and laboratory space at 140 First Street. Under the agreements, the Company has received rental income of $1.4 million for the year ended December 31, 2023. Such rental income was reflected as a reduction of research and development expense and general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. There were no outstanding receivables due from the subtenants as of December 31, 2023.

In September 2020, the Company sublet the entire space of its 325 Vassar Street facility, approximately 19,404 square feet, to Sail Bio (formerly known as LARONDE, Inc. and 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 $1.6 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 $2.5 million and $2.3 million during the years ended December 31, 2023 and 2022, respectively, which was recorded within research and development expense and general and administrative expense in the consolidated statements of operations and comprehensive loss. There was no outstanding receivable due from Sail Bio as of December 31, 2023 and December 31, 2022.

In July 2020, the Company entered into a Shared Space Arrangement (the Arrangement) with Sail Bio to share one-third of Sail Bio's 69,867 square feet of leased space at 20 Acorn Park Drive, Cambridge, Massachusetts. In January 2022, the Company entered into an amendment to the Arrangement with Sail Bio to exercise the option to renew the lease through July 2023. In connection with the amendment, the Company made an upfront payment of $2.9 million in January 2022, to cover the rent payments for the extended lease term. Additionally, upon the expiration of the extended lease term, the Company received $0.65 million from Sail Bio for all furniture, fixtures and equipment owned by the Company that will remain at the lease property. The net book value of these assets was determined to be $0.4 million, and the Company recognized a gain on this disposal of $0.2 million in June 2023 since the assets are no longer in service, which was recorded in other income (expense), net in the consolidated statements of operations and comprehensive loss.

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 was to continue on a month-to-month basis until advanced notice is provided to the Company. Cygnal gave notice, terminated the agreement and vacated the property in May 2022. The rental rate for the sublease arrangement was equal to the Company's rental obligation per the agreement with BMR-325 Vassar Street LLC, approximating $0.1 million per year. The sublessee was 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 less than $0.1 million for the year ended December 31, 2022, which was recorded as a reduction of rental expenses. Such rental income was reflected as a reduction of research and development expense and general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. There was no outstanding receivable due from Cygnal as of December 31, 2022.

Refer to other related party transactions as described in Note 9, *Commitments and contingencies*, Note 10, *License agreements* and Note 11, *Collaboration agreements*.

17. 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. On May 1, 2022, the Company began matching 50% of employee contributions of up to 6% of eligible compensation contributed on a pre-tax and/or Roth after-tax basis to the 401(k) Plan. During the years ended December 31, 2023 and 2022, the Company made matching contributions totaling $0.6 million and $0.5 million, respectively.

Employment Agreement

This Employment Agreement (this "Agreement"), dated as of April 28, 2022, is made by and between Omega Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and Joshua Reed ("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 May 23, 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 Financial 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 $450,000 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 one-time first year sign-on bonus in the amount of $130,000 (the "First Year Bonus"), payable in a lump sum on the first scheduled payroll date following the Start Date. Notwithstanding the foregoing, if 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 six months of the Start Date, Executive will repay the Company the full amount of the First Year Bonus, or, if Executive's employment is terminated by the Company for Cause or by Executive other than for Good Reason, in either case more than 6 months but less than twelve months from the Start Date, Executive will repay the Company an amount equal to 50% of the First Year Bonus. 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 320,000 shares 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.

(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 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;

(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 substantially perform the duties associated with Executive's position with the Company or 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 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 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.

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 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.

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 4 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 other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[*Signature Page Follows*]

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 Chief Executive Officer

EXECUTIVE
/s/ Joshua Reed
Joshua Reed

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 __, 2022 (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 __, 2022 (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 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 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.

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:

Joshua Reed

OMEGA THERAPEUTICS, INC.

Dated:

By:

Name:

Title:

EXHIBIT B

Restrictive Covenant Agreement

[attached]

Exhibit 10.12

October 5, 2022

Richard A. Young, Ph.D.
1 Longfellow Place, Apt. 3510
Boston, MA 02114

Re: **Amendment #3 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, 2023, 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, 2023 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/ Thomas McCauley
Thomas McCauley
Chief Scientific Officer

Agreed:

/s/ Richard A. Young
Name: Richard A. Young, Ph.D.

Exhibit 10.13

October 6, 2023

Richard A. Young, Ph.D.
1 Longfellow Place, Apt. 3510
Boston, MA 02114

Re: **Omega / Young - Amendment #4 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, 2024, 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, 2024 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/ Thomas McCauley
Thomas McCauley
Chief Scientific Officer

Agreed:

/s/ Richard A. Young
Name: Richard A. Young, Ph.D.

Exhibit 10.18

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Executed Version
Confidential

OMEGA THERAPEUTICS, INC.
140 First Street, Suite 501
Cambridge, MA 02141

December 31, 2023

Flagship Pioneering Innovations V, Inc. c/o
Flagship Pioneering, Inc.
55 Cambridge Parkway, Suite 800E
Cambridge, MA 02142
Attention: Legal Notices

Re: Letter Agreement re License Agreement Dear
Sir or Madam:

Reference is hereby made to that certain License Agreement by and between Flagship Pioneering Innovations V, Inc. ("**Flagship**") and Omega Therapeutics, Inc. ("**Company**"), dated effective as of March 12, 2019, as amended from time to time (the "**License Agreement**"), pursuant to which Company obtained from Flagship certain rights to Foundational IP in order to develop and commercialize Licensed Products (as each term is defined in the License Agreement). Company is currently negotiating a Research Collaboration Agreement to be entered into by and among Company, Novo Nordisk A/S ("**Novo Nordisk**") and a newly formed wholly owned subsidiary of Pioneering Medicine (NN), LLC ("**SpinCo**"), and certain entities affiliated with SpinCo, pursuant to which Company will grant Novo Nordisk and SpinCo certain rights under the Foundational IP (the "**Research Collaboration Agreement**" and such transactions contemplated by the Research Collaboration Agreement, the "**Proposed Transaction**"). Capitalized terms not otherwise defined in this letter agreement (this "**Letter Agreement**") shall have the meanings set forth in the License Agreement. In connection with the Proposed Transaction, as of the date first written above (the "**Letter Agreement Effective Date**"), Flagship and Company hereby agree as follows:

1) Assignment of Foundational IP to Flagship. Notwithstanding anything set forth in Sections 2.1 and 2.3(a) of the License Agreement, Flagship hereby acknowledges and agrees that solely with respect to the Research Collaboration Agreement, ownership of, and rights in and to (including the rights to Prosecute and enforce), Foundational IP arising from such Research Collaboration Agreement shall be governed by the terms and conditions of the Research Collaboration Agreement, and as it relates to clause (b) in the definition of Foundational IP in Section 1.17 of the License Agreement, Company shall only be required to assign to Flagship,

the rights, title and interests Company holds in and to such Foundational IP pursuant to the Research Collaboration Agreement.

2) Sublicensing. Pursuant to Section 2.3(b) of the License Agreement, Company hereby notifies Flagship that Company is currently negotiating the Research Collaboration Agreement, pursuant to which Company will grant Novo Nordisk and SpinCo a Sublicense under the Foundational IP. Solely with respect to the Research and Collaboration Agreement, Flagship hereby waives the requirement under Section 2.3(b) of the License Agreement that [***].

3) Retained Rights; License Back. The last sentence of Section 2.6 of the License Agreement is hereby deleted in its entirety and replaced with the following sentence:

> Company hereby grants to Flagship a non-exclusive, royalty-free, fully paid, sublicensable (to Flagship Entities and service providers thereof) license to practice, and to permit Flagship Entities to practice, the Foundational IP within the Licensed Field in the Territory for non-commercial research and non-clinical development purposes or to perform under the Managerial Agreement, in each case except for the purpose of targeting the Initial Program Target, Program Target or any Proposed Backup Target (as such terms are defined in the Research Collaboration Agreement), for so long as such target remains an Initial Program Target, Program Target or Proposed Backup Target, as applicable, under the Research Collaboration Agreement. "Research Collaboration Agreement" means that certain Research Collaboration Agreement entered into by and among Company, Novo Nordisk A/S, and a newly formed wholly owned subsidiary of Pioneering Medicine (NN), LLC ("SpinCo"), and certain entities affiliated with SpinCo, pursuant to which Company will grant Novo Nordisk and SpinCo certain rights under the Foundational IP.

4) Reserved.

5) Royalties. Notwithstanding anything set forth in the License Agreement (including Sections 2.3(c) and 4.1 thereof), Flagship hereby waives Company's obligation to pay to Flagship [***]% of Net Sales with respect to Licensed Products sold by Novo Nordisk or its Affiliates (as defined in the Research Collaboration Agreement) or Sublicensees (as defined in the Research Collaboration Agreement) pursuant to the Research Collaboration Agreement. In furtherance thereof, Flagship hereby waives Company's reporting requirements under Article 5 of the License Agreement with respect to any activities conducted under the Research Collaboration Agreement.

6) Procedures. The License Agreement is hereby amended solely with respect to rights and obligations of the Parties thereunder as applied to the parties under the Research Collaboration Agreement, and such parties' performance thereunder, as follows:

   a) The second sentence of Section 8.2(a) of the License Agreement is hereby deleted and replaced with the following sentence:

If, within [***] ([***]) [***] after becoming aware of any suspected infringement or Infringement Action, Company has not commenced to initiate, defend, or otherwise resolve such Infringement Action (to the extent Company has the right to do so pursuant to the Research Collaboration Agreement), then [***] shall have the right, but not the obligation, to initiate, control, prosecute, and/or defend such Infringement Action at its own expense.

7) Patent Challenge. The License Agreement is hereby amended solely with respect to the Research Collaboration Agreement as follows:

a) Section 12.2(c)(i) of the License Agreement is hereby deleted and replaced with the following sentence:

"Except to the extent that this Section 12.2(c)(i) is unenforceable under applicable laws of the applicable jurisdiction where the applicable Patents within the Foundational IP are pending or issued, Flagship has the right to terminate this Agreement in its entirety upon written notice to Company in the event that Company or any of its Subsidiaries or its or their Sublicensees (each, a "**Patent Challenging Party**") directly or indirectly brings a Patent Challenge with respect to any Patent within the Foundational IP; provided that (i) this Section 12.2(c)(i) shall not apply to any Patent Challenge that is (A) first made by a Patent Challenging Party in defense of a claim of patent infringement under the applicable Patent within the Foundational IP or (B) made in ordinary course Prosecution activities to distinguish the inventions claimed in any Patent Controlled by Company or its Subsidiary from those claimed or disclosed in any Patent within the Foundational IP or to respond to citation of a Patent within the Foundational IP by a patent office in a rejection against any Patent Controlled by Company or its Subsidiary, (ii) Flagship shall not have the right to terminate this Agreement under this Section 12.2(c)(i) if Company (A) causes the Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws or causes its Subsidiary or Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (B) in the case of a Patent Challenge brought by a Sublicensee, terminates such Sublicensee's sublicense to the Patent within the Foundational IP being challenged by the Sublicensee, in each case ((A) and (B)), within [***] ([***]) [***] following Flagship's notice to Company under this Section 12.2(c)(i), (iii) this Section 12.2(c)(i) shall not apply to any Patent Challenge that is due to the Patent Challenging Party responding to a court request, subpoena, or order, or an administrative agency request or order, or the applicable proceeding is initiated by a Patent office and not at the instigation of the Patent Challenging Party, and (iv)

this Section 12.2(c)(i) shall not apply to any Patent Challenge that was initiated by a Third Party that subsequently becomes an affiliate of Company if (A) such Patent Challenge was initiated [***] before the closing of the transaction whereby such Third Party became an affiliate of Company, or (B) if such Patent Challenge was initiated within any such [***] , if Company causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws or causes such Third Party to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge. For purposes of this Section 12.2(c)(i),
"**Patent Challenge**" means a legal or administrative proceeding challenging the patentability, enforceability or validity of any Patent within the Foundational IP.

b) Section 12.2(c)(ii) of the License Agreement is hereby deleted in its entirety and replaced with the following new Section 12.2(c)(ii):

"Company shall include provisions in all Sublicenses consistent with the terms of Section 12.2(c)(i). The failure to include such provisions in a Sublicense shall constitute a material breach of this Agreement."

8) Research Collaboration Agreement. Flagship hereby acknowledges that it has received and reviewed the draft of the Research Collaboration Agreement dated December 31, 2023, and hereby agrees that, after giving effect to the provisions of this Letter Agreement, such draft complies with all applicable requirements of the License Agreement and includes or references all terms, conditions, obligations and provisions of the License Agreement (giving effect to the provisions of this Letter Agreement) applicable to the Research Collaboration Agreement with which Novo Nordisk, its Affiliates (as defined in the Research Collaboration Agreement) and their respective Sublicensees (as defined in the Research Collaboration Agreement) are required to comply. Flagship hereby acknowledges and agrees that by consummating the Research Collaboration Agreement, notwithstanding anything to the contrary under the License Agreement, Company has met and will be deemed to have met all of its diligence obligations under Article 3 of the License Agreement for so long as Company and Novo Nordisk fulfill their respective obligations under the Research Collaboration Agreement, and Flagship will not exercise its rights under Section 2.7 of the License Agreement with respect to the Sub-Field that is the Field of the Research Collaboration Agreement. Flagship further hereby acknowledges that Company and Novo Nordisk are relying on this Letter Agreement and would not be entering into the Research Collaboration Agreement but for the acknowledgements and amendments agreed to by Flagship in this Letter Agreement.

9) Termination. This Letter Agreement shall terminate effective immediately upon the earliest of: (a) mutual agreement of PM and Company to terminate this Letter Agreement, (b) if Company,

SpinCo and Novo Nordisk elect not to, or do not, execute the Research Collaboration Agreement, and (c) the expiration or termination of the Research Collaboration Agreement. Notwithstanding the foregoing, the following provisions shall survive expiration or termination of this Letter Agreement: paragraphs 8, 9, 10 and 11.

10) Assignment. This Letter Agreement may not be assigned, nor may any right or obligation hereunder be assigned, by a party without the prior written consent of the other party, except that either party may make such assignment without the other party's prior written consent together with the assignment of the License Agreement in accordance with Section 14.5 of the License Agreement. Any assignment or attempted assignment by a party in violation of the terms of this paragraph shall be null, void and of no legal effect.

11) Miscellaneous. The provisions of Sections 14.4 (Modification, Waiver and Remedies), 14.8 (Headings and Counterparts), 14.9 (Governing Law; Venue) and 14.10 (Integration) of the License Agreement are hereby incorporated into this Letter Agreement by reference and shall apply to this Letter Agreement, *mutatis mutandis*.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have caused this Letter Agreement to be duly executed by their respective duly authorized officers as of the Letter Agreement Effective Date.

Sincerely,

OMEGA THERAPEUTICS, INC.

By: /s/ Mahesh Karande Name:
Mahesh Karande
Title: President and Chief Executive Officer

Agreed and accepted by:

FLAGSHIP PIONEERING INNOVATIONS V, INC.

By: /s/ Noubar Afeyan
Name: Noubar Afeyan
Title: President

Exhibit 10.20

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Confidential

Effective December 31, 2023 Omega Therapeutics, Inc.
140 First Street, Suite 501
Cambridge, Massachusetts 02141

Re: Waiver, Confirmation and Agreement Regarding Research Collaboration Agreement

Ladies and Gentlemen:

Reference is made to the Patent License Agreement between Whitehead Institute for Biomedical Research ("Whitehead") and Omega Therapeutics, Inc. ("Omega") effective as of May 22, 2019 (the "Exclusive License Agreement"; Whitehead Ref: L7085). Capitalized terms used in this letter agreement (this "Letter") without definition shall have the meanings given to them in the Exclusive License Agreement. All references to Sections herein are to Sections in the Exclusive License Agreement unless otherwise stated.

Pursuant to a research collaboration agreement (the "Research Collaboration Agreement") that Omega intends to enter into with Novo Nordisk A/S ("Novo Nordisk") and certain entities affiliated with Flagship Pioneering, Inc. ("Flagship"), Omega would grant Novo Nordisk an exclusive sublicense under Omega's rights under the Exclusive License Agreement to exploit certain products for the prevention, treatment or control of a cardiometabolic disease (including, for the avoidance of doubt, diabetes) in humans. The foregoing sublicense proposed to be granted by Omega to Novo Nordisk under the Research Collaboration Agreement is referred to herein as the "Sublicense." Whitehead hereby acknowledges that it has received and reviewed the draft Research Collaboration Agreement dated December 31, 2023 (the "Draft Research Collaboration Agreement"). For purposes of this Letter, "RCA Licensed Products" shall be used to refer to "Licensed Products" as defined in Section 1.148 of the Research Collaboration Agreement.

As a condition to entering into the Research Collaboration Agreement, Novo Nordisk has requested that Omega obtain from Whitehead a waiver, confirmation and agreement regarding certain provisions of the Exclusive License Agreement as they apply to the Sublicense, the Research Collaboration Agreement and Omega's ability to comply with the terms of the Exclusive License Agreement. Whitehead wishes to comply with that request on the terms set forth herein to encourage and promote the development of the Patent Rights licensed to Omega pursuant to the Exclusive License Agreement. Whitehead is providing the waivers and other confirmations and agreements herein for the benefit of Omega and Novo Nordisk.

1. Effectiveness of this Letter

This Letter will be effective upon the effective date of the Research Collaboration Agreement and will terminate upon the earlier of the expiration or termination of the Research Collaboration Agreement; *provided, however*, that nothing herein shall be construed to extend the Term of the Exclusive License Agreement.

2. Sublicenses

Section 2.3.1(a) of the Exclusive License Agreement requires Sublicensees to make payments due to Omega in a timely manner, so that Omega may comply with its obligations to make payments to Whitehead as set forth in Article 4 of the Exclusive License Agreement. Whitehead hereby acknowledges and agrees that the timing of Omega's obligations to make payments to Whitehead as set forth in Article 4 of the Exclusive License Agreement is being modified pursuant to this Letter and that, after giving effect to such modifications, the Research Collaboration Agreement complies with Section 2.3.1(a) of the Exclusive License Agreement.

Whitehead hereby acknowledges and agrees that Section 2.5(d) of the Exclusive License Agreement does not need to be binding on Novo Nordisk because Novo Nordisk is party to that certain Sponsored Research Agreement between Whitehead and Novo Nordisk A/S, dated December 15, 2017.

Novo Nordisk has informed Omega that Novo Nordisk maintains a program of self-insurance. For purposes of Sections 2.3.1(c) as it relates to insurance only and 8.2 of the Exclusive License Agreement solely as they apply to the Research Collaboration Agreement (and not for any other purpose):
(i) Whitehead hereby approves Novo Nordisk's self-insurance program provided that it meets the limits described in Section 8.2 of the Exclusive License Agreement; and (ii) for so long as Novo Nordisk maintains such self-insurance with such limits, Whitehead waives the application of Sections 2.3.1(c) as it relates to insurance only and 8.2 to Omega and Novo Nordisk in connection with the Research Collaboration Agreement. For the avoidance of doubt, Section 2.3.1(c) as it relates to indemnification is not waived.

3. Diligence Requirements

For purposes of Section 3.1(ii) of the Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that the report required by Section 3.1(ii) of the Exclusive License Agreement will not be required to contain a discussion of intended efforts and sales projections for the year in which the report is submitted.

Whitehead hereby acknowledges and agrees that the Research Collaboration Agreement is a bona fide Sublicense Agreement to develop Licensed Products pursuant to Section 3.2(a) of the Exclusive License Agreement.

4. Milestone Payments

For purposes of Section 4.1(c) of the Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that Omega shall pay the applicable Milestone Payments to Whitehead within [***] ([***]) [***] of Omega's receipt of notification of such Milestone Payment triggering events by Novo Nordisk pursuant to the Research Collaboration Agreement.

5. Running Royalties on Licensed Products

For purposes of Sections 1.10 and 4.1(d) of the Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that the running royalty of [***] percent ([***]%) payable thereunder shall be calculated using the definition of "Net Sales" set forth in Section 1.163 of the Research Collaboration Agreement instead of the definition of Net Sales set forth in Section 1.10 of the Exclusive License Agreement.

For purposes of Section 4.1(d) of the Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that the running royalties will be payable for each Reporting Period and will be due to Whitehead within [***] ([***]) [***] following Omega's receipt of royalty payments pursuant to Section 8.5.3 of the Research Collaboration Agreement.

6. Sublicense Income

For purposes of Section 4.1(f) of the Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that the applicable amounts will be payable for each Reporting Period and will be due to Whitehead within [***] ([***]) [***] following Omega's receipt of any payments under the Research Collaboration Agreement that would constitute Sublicense Income under the Research Collaboration Agreement.

7. Reports and Record Keeping

For purposes of Sections 5.1(a) and 5.1(c) of the Exclusive License Agreement solely as they apply to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that Omega will be permitted to deliver such reports to Whitehead within [***] ([***]) [***] following Omega's receipt of reports from Novo Nordisk pursuant to Section 8.5.3 of the Research License Agreement containing information necessary for Omega to provide the information required by Section 5.2 of the Exclusive License Agreement (as modified by this Letter).

For purposes of Section 5.1(b) of the Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that Omega will be permitted to report to Whitehead the date of first commercial sale of a Licensed Product within [***] ([***]) [***] of Omega's receipt of notice of such event pursuant to Section 4.3.2 of the Research Collaboration Agreement.

For purposes of Section 5.2 of the Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under

the Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that such reports shall not be required to include (i) the gross price charged by Novo Nordisk or its Affiliates or Sublicensees for each Licensed Product, (ii) an itemized listing of applicable deductions from the calculation of Net Sales, or (iii) the achievement of Omega's Diligence Obligations under Article 3 and Milestones under Section 4.1(c) of the Exclusive License Agreement. In addition, Whitehead hereby acknowledges and agrees that the calculation of Net Sales in such report shall be calculated using the definition of "Net Sales" set forth in Section 1.163 of the Research Collaboration Agreement rather than the definition of Net Sales set forth in Section 1.10 of the Exclusive License Agreement

8. Research Collaboration Agreement.

Whitehead hereby acknowledges that it has received and reviewed the draft of the Research Collaboration Agreement dated December 31, 2023, and hereby agrees that, after giving effect to the provisions of this Letter, such draft complies with all applicable requirements of the Exclusive License Agreement (including Section 2.3 and Article 8 thereof) and includes or references all terms, conditions, obligations and provisions of the Exclusive License Agreement (giving effect to the provisions of this Letter) applicable to the Research Collaboration Agreement with which Novo Nordisk, its Affiliates and their respective Sublicensees are required to comply. Whitehead further hereby acknowledges that Omega and Novo Nordisk are relying on this Letter and would not be entering into the Research Collaboration Agreement but for the acknowledgements and amendments agreed to by Whitehead in this Letter.

[*signature page follows*]

Very truly yours,

Whitehead Institute for Biomedical Research

By: /s/ Carla DeMaria
Name: Carla DeMaria
Title: Director of Intellectual Property & Sponsored Programs

Acknowledged and Agreed:

Omega Therapeutics, Inc.

By: /s/ Mahesh Karande
Name: Mahesh Karande
Title: President and CEO

[Signature Page to Waiver, Confirmation and Agreement Letter Regarding Exclusive License Agreement]

Exhibit 10.22

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Confidential

Effective December 31, 2023 Omega Therapeutics, Inc.
140 First Street, Suite 501
Cambridge, Massachusetts 02141

Re: Waiver, Confirmation and Agreement Regarding Research Collaboration Agreement

Ladies and Gentlemen:

Reference is made to the Patent License Agreement (Co-Exclusive) between Whitehead Institute for Biomedical Research ("Whitehead") and Omega Therapeutics, Inc. ("Omega") effective as of May 22, 2019 (the "Co-Exclusive License Agreement"; Whitehead Ref: L7516). Capitalized terms used in this letter agreement (this "Letter") without definition shall have the meanings given to them in the Co-Exclusive License Agreement. All references to Sections herein are to Sections in the Co-Exclusive License Agreement unless otherwise stated.

Pursuant to a research collaboration agreement (the "Research Collaboration Agreement") that Omega intends to enter into with Novo Nordisk A/S ("Novo Nordisk") and certain entities affiliated with Flagship Pioneering, Inc. ("Flagship"), Omega would grant Novo Nordisk an exclusive sublicense under Omega's rights under the Co-Exclusive License Agreement to exploit certain products for the prevention, treatment or control of a cardiometabolic disease (including, for the avoidance of doubt, diabetes) in humans. The foregoing sublicense proposed to be granted by Omega to Novo Nordisk under the Research Collaboration Agreement is referred to herein as the "Sublicense." Whitehead hereby acknowledges that it has received and reviewed the draft Research Collaboration Agreement dated December 31, 2023 (the "Draft Research Collaboration Agreement"). For purposes of this Letter, "RCA Licensed Products" shall be used to refer to "Licensed Products" as defined in Section 1.148 of the Research Collaboration Agreement.

As a condition to entering into the Research Collaboration Agreement, Novo Nordisk has requested that Omega obtain from Whitehead a waiver, confirmation and agreement regarding certain provisions of the Co-Exclusive License Agreement as they apply to the Sublicense, the Research Collaboration Agreement and Omega's ability to comply with the terms of the Co-Exclusive License Agreement. Whitehead wishes to comply with that request on the terms set forth herein to encourage and promote the development of the Patent Rights licensed to Omega pursuant to the Co-Exclusive License Agreement. Whitehead is providing the waivers and other confirmations and agreements herein for the benefit of Omega and Novo Nordisk.

1. Effectiveness of this Letter

This Letter will be effective upon the effective date of the Research Collaboration Agreement and will terminate upon the earlier of the expiration or termination of the Research Collaboration Agreement; *provided, however*, that nothing herein shall be construed to extend the Term of the Co-Exclusive License Agreement.

2. Sublicenses

Section 2.3.1(a) of the Co-Exclusive License Agreement requires Sublicensees to make payments due to Omega in a timely manner, so that Omega may comply with its obligations to make payments to Whitehead as set forth in Article 4 of the Co-Exclusive License Agreement. Whitehead hereby acknowledges and agrees that the timing of Omega's obligations to make payments to Whitehead as set forth in Article 4 of the Co-Exclusive License Agreement is being modified pursuant to this Letter and that, after giving effect to such modifications, the Research Collaboration Agreement complies with Section 2.3.1(a) of the Co-Exclusive License Agreement.

Whitehead hereby acknowledges and agrees that Section 2.5(d) of the Co-Exclusive License Agreement does not need to be binding on Novo Nordisk because Novo Nordisk is party to that certain Sponsored Research Agreement between Whitehead and Novo Nordisk A/S, dated December 15, 2017.

Novo Nordisk has informed Omega that Novo Nordisk maintains a program of self-insurance. For purposes of Sections 2.3.1(c) as it relates to insurance only and 8.2 of the Co-Exclusive License Agreement solely as they apply to the Research Collaboration Agreement (and not for any other purpose):
(i) Whitehead hereby approves Novo Nordisk's self-insurance program provided that it meets the limits described in Section 8.2 of the Co-Exclusive License Agreement; and (ii) for so long as Novo Nordisk maintains such self-insurance with such limits, Whitehead waives the application of Sections 2.3.1(c) as it relates to insurance only and 8.2 to Omega and Novo Nordisk in connection with the Research Collaboration Agreement. For the avoidance of doubt, Section 2.3.1(c) as it relates to indemnification is not waived.

3. Diligence Requirements

For purposes of Section 3.1(ii) of the Co-Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Co-Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that the report required by Section 3.1(ii) of the Co-Exclusive License Agreement will not be required to contain a discussion of intended efforts and sales projections for the year in which the report is submitted.

Whitehead hereby acknowledges and agrees that the Research Collaboration Agreement is a bona fide Sublicense Agreement to develop Licensed Products pursuant to Section 3.2(a) of the Co-Exclusive License Agreement.

4. Milestone Payments

For purposes of Section 4.1(c) of the Co-Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Co-Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that Omega shall pay the applicable Milestone Payments to Whitehead within
[***] ([***]) [***] of Omega's receipt of notification of such Milestone Payment triggering events by

Novo Nordisk pursuant to the Research Collaboration Agreement.

5. Running Royalties on Licensed Products

For purposes of Sections 1.9 and 4.1(d) of the Co-Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Co-Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that the running royalty of [***] percent ([***]%) payable thereunder shall be calculated using the definition of "Net Sales" set forth in Section 1.163 of the Research Collaboration Agreement instead of the definition of Net Sales set forth in Section 1.9 of the Co-Exclusive License Agreement.

For purposes of Section 4.1(d) of the Co-Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Co-Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that the running royalties will be payable for each Reporting Period and will be due to Whitehead within [***] ([***]) [***] following Omega's receipt of royalty payments pursuant to Section 8.5.3 of the Research Collaboration Agreement.

6. Reports and Record Keeping

For purposes of Sections 5.1(a) and 5.1(c) of the Co-Exclusive License Agreement solely as they apply to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Co-Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that Omega will be permitted to deliver such reports to Whitehead within [***]
([***]) [***] following Omega's receipt of reports from Novo Nordisk pursuant to Section 8.5.3 of the Research License Agreement containing information necessary for Omega to provide the information required by Section 5.2 of the Co-Exclusive License Agreement (as modified by this Letter).

For purposes of Section 5.1(b) of the Co-Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Co-Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that Omega will be permitted to report to Whitehead the date of first commercial sale of a Licensed Product within [***] ([***]) [***] of Omega's receipt of notice of such event pursuant to Section 4.3.2 of the Research Collaboration Agreement.

For purposes of Section 5.2 of the Co-Exclusive License Agreement solely as it applies to RCA Licensed Products under the Research Collaboration Agreement that would be considered Licensed Products under the Co-Exclusive License Agreement (and not for any other purpose), Whitehead hereby acknowledges and agrees that such reports shall not be required to include (i) the gross price charged by Novo Nordisk or its Affiliates or Sublicensees for each Licensed Product, (ii) an itemized listing of applicable deductions from the calculation of Net Sales, or (iii) the achievement of Omega's Diligence Obligations under Article 3 and Milestones under Section 4.1(c) of the Co-Exclusive License Agreement.
In addition, Whitehead hereby acknowledges and agrees that the calculation of Net Sales in such report shall be calculated using the definition of "Net Sales" set forth in Section 1.163 of the Research

Collaboration Agreement rather than the definition of Net Sales set forth in Section 1.9 of the Co-Exclusive License Agreement

7. Research Collaboration Agreement.

Whitehead hereby acknowledges that it has received and reviewed the draft of the Research Collaboration Agreement dated December 31, 2023, and hereby agrees that, after giving effect to the provisions of this Letter, such draft complies with all applicable requirements of the Co-Exclusive License Agreement (including Section 2.3 and Article 8 thereof) and includes or references all terms, conditions, obligations and provisions of the Co-Exclusive License Agreement (giving effect to the provisions of this Letter) applicable to the Research Collaboration Agreement with which Novo Nordisk, its Affiliates and their respective Sublicensees are required to comply. Whitehead further hereby acknowledges that Omega and Novo Nordisk are relying on this Letter and would not be entering into the Research Collaboration Agreement but for the acknowledgements and amendments agreed to by Whitehead in this Letter.

[*signature page follows*]

Very truly yours,

Whitehead Institute for Biomedical Research

By: /s/ Carla DeMaria
Name: Carla DeMaria
Title: Director of Intellectual Property & Sponsored Programs

Acknowledged and Agreed:

Omega Therapeutics, Inc.

By: /s/ Mahesh Karande
Name: Mahesh Karande
Title: President and CEO

[Signature Page to Waiver, Confirmation and Agreement Letter Regarding Co-Exclusive License Agreement]

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Exhibit 10.33

RESEARCH COLLABORATION AGREEMENT

by and among

PIONEERING MEDICINES 08, INC.
a Delaware corporation,

OMEGA THERAPEUTICS, INC.
a Delaware corporation,

PIONEERING MEDICINES (NN), LLC
a Delaware limited liability company,

PM (NN) EXPLORATIONS, INC.
a Delaware corporation,

and

NOVO NORDISK A/S
a corporation organized and existing under the laws of Denmark

Dated as of December 31, 2023

TABLE OF CONTENTS

RESEARCH COLLABORATION AGREEMENT

This RESEARCH COLLABORATION AGREEMENT (this "**Agreement**") is made and entered into as of December 31, 2023 (the "**Effective Date**"), by and among Pioneering Medicines 08, Inc., a Delaware corporation located at 55 Cambridge Pkwy, Suite 800E, Cambridge, MA 02142 ("**PM SpinCo**"), Omega Therapeutics, Inc., a Delaware corporation located at 140 First Street, Suite 501, Cambridge, Massachusetts 02140 ("**PlatformCo**," and together with PM SpinCo, each an "**RCA PM Party**" and collectively, the "**RCA PM Parties**") and Novo Nordisk A/S, a corporation organized and existing under the laws of Denmark located at Novo Allé 1, 2880 Bagsvaerd, Denmark ("**Novo Nordisk**" and, together with the RCA PM Parties, the "**Parties**," and individually each a "**Party**"). In addition, Pioneering Medicines (NN), LLC, a Delaware limited liability company ("**Shareholder**") shall be a party to this Agreement (and therefore a Party) solely for purposes of Sections 6.1.1, 6.2, 11.1, 11.4, 11.5, 12.1, 12.4, 12.5, 12.6.1, 12.7 through 12.12, 15.1 through 15.4, 15.5.1, 15.6 through 15.8 and 15.10 through 15.13, and PM (NN) Explorations, Inc., a Delaware corporation ("**PMCo**") shall be a party to this Agreement (and therefore a Party) solely for purposes of Sections 6.1.1, 6.2, 11.1, 11.4, 11.5, 12.1, 12.4, 12.6.1, 12.7 through 12.12, 13.3.3(c), 13.3.3(d), 13.3.3(g), 15.1 through 15.4, 15.5.1, 15.6 through 15.8 and 15.10 through 15.13.

RECITALS

WHEREAS, PlatformCo has developed a proprietary platform for discovering and developing epigenetic/epigenomic controllers that directly or indirectly regulate the expression of one or more Genes (as defined below) via epigenetic/epigenomic modification of an Insulated Genomic Domain (as defined below) for use in the treatment of human diseases;

WHEREAS, Novo Nordisk is a pharmaceutical company with expertise in research, development and commercialization of pharmaceutical products;

WHEREAS, in connection with the execution of this Agreement, Novo Nordisk, PM SpinCo and Shareholder (as defined below) have executed a separate Shareholder Option Agreement of even date herewith (the "**Option Agreement**") pursuant to which Shareholder has granted to Novo Nordisk an exclusive, irrevocable option to purchase from Shareholder one hundred percent (100%) of the issued and outstanding shares of capital stock of PM SpinCo (the "**Option**"), subject to the terms and conditions set forth in the Option Agreement and the Share Purchase Agreement (as defined below); and

WHEREAS, Novo Nordisk desires to enter into an arrangement with the RCA PM Parties pursuant to which the Parties shall conduct the Program (as defined below) in accordance with the R&D Plan and R&D Budget (as each term is defined below) for the purpose of assisting Novo Nordisk in determining whether to exercise the Option pursuant to the terms and conditions of the Option Agreement and the Share Purchase Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS.

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meanings set forth below.

1.1 "**Accounting Standards**" means International Financial Reporting Standards ("**IFRS**"), United States generally accepted accounting principles ("**US GAAP**"), or any other internationally recognized accounting standards, in each case as generally and consistently applied.

1.2 "**Acquired Competing Product**" has the meaning set forth in Section 6.2.1.

1.3 "**Acquisition Transaction**" has the meaning set forth in Section 6.2.1.

1.4 "**Action**" means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

1.5 "**Affiliate**" means, with respect to any Person, any entity controlling, controlled by or under common control with such first Person, at the time that the determination of affiliation is made and for as long as such control exists. For purposes of this definition, "control" means (a) direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under Applicable Laws; *provided*, *however*, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership, or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Affiliates of a Party exclude Persons who are financial investors of such Party or under common control with such financial investors other than such Party and its Subsidiaries. Further, for the

purposes of this definition, (i) Novo Holdings A/S, the Novo Nordisk Foundation and their respective Affiliates (other than Novo Nordisk and its Subsidiaries, including PM SpinCo after the Closing Date) shall not be considered Affiliates of Novo Nordisk, (ii) Flagship Affiliates shall not be considered Affiliates of PlatformCo, PM SpinCo, PMCo or Shareholder (or any of such Persons' Subsidiaries), and (iii) PlatformCo or its Subsidiaries shall not be considered Affiliates of PM SpinCo or its Subsidiaries, or of PMCo or its Subsidiaries or of Shareholder or its Subsidiaries.

1.6 "**Affiliate Core IP**" means any Core IP that is Controlled by a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries.

1.7 "**Affiliate Core Patents**" means the Core Patents constituting Affiliate Core IP.

1.8 "**Agreement**" has the meaning set forth in the preamble.

1.9 "**Alliance Manager(s)**" has the meaning set forth in Section 2.8.

1.10 "**Antitrust Clearance Date**" has the meaning set forth in the Share Purchase Agreement.

1.11 "**Antitrust Filings**" has the meaning set forth in the Share Purchase Agreement.

1.12 "**Applicable Laws**" means any applicable federal, state, local or other domestic or foreign or supranational law (including common law), statute, ordinance, rule, regulation, judgment, order, writ, decree or other court orders, or other requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Authority.

1.13 "**Audited Party**" has the meaning set forth in Section 8.6.1.

1.14 "**Auditing Party**" has the meaning set forth in Section 8.6.1.

1.15 "**Auditor**" has the meaning set forth in Section 8.6.1.

1.16 "**Background IP**" has the meaning set forth in Section 10.2.

1.17 "**Background Licensed Product-Specific Patents**" has the meaning set forth in Section 10.4.4(a).

1.18 "**Backup Target**" means the Proposed Backup Target that Novo Nordisk has elected to become a Backup Target in accordance with Section 3.3.1.

1.19 "**Backup Target Validation Studies**" means R&D Activities that validate the Proposed Backup Targets against the criteria set forth in Schedule 1.19.

1.20 "**Backup Target Validation Studies Data Package**" means a data package containing the subject matter set forth in Schedule 1.20.

1.21 "**Bankruptcy Event**" has the meaning set forth in Section 13.2.4.

1.22 "**Base Term**" has the meaning set forth in Section 1.273.

1.23 "**Baseball Arbitrator**" has the meaning set forth in Schedule 13.3.3(d).

1.24 "**BLA**" has the meaning set forth in the definition of MAA.

1.25 "**Breaching Party**" has the meaning set forth in Section 13.2.3(c).

1.26 "**Breaching PM Party**" has the meaning set forth in Section 13.2.3(a).

1.27 "**Business Day**" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York or Copenhagen, Denmark are authorized or obligated by Applicable Laws to close.

1.28 "**Calendar Quarter**" means each of the three (3) month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; *provided*, *however*: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the Calendar Quarter in which the Effective Date occurs; and (b) the last Calendar Quarter shall extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

1.29 "**Calendar Year**" means, for the first Calendar Year, the period beginning on the Effective Date and ending on December 31, 2023, and for each Calendar Year thereafter each twelve (12)-month period commencing on January 1, and ending on December 31, except that the last Calendar Year shall commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.

1.30 [***].

1.31 "**Chairperson**" has the meaning set forth in Section 2.3.

1.32 "**Change of Control**" means, with respect to a Party: (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of

the surviving entity or the parent of the surviving entity immediately after such merger or consolidation; (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party; or (c) the sale, exchange, lease, contribution, disposition, or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates. Notwithstanding the foregoing, with respect to a Party, the term "Change of Control" shall not include any sale of shares of capital stock of such Party, in a single transaction or series of related transactions in which such Party issues new securities solely to institutional investors for cash or the cancellation or conversion of indebtedness or a combination thereof where such transaction(s) are conducted for bona fide Equity Financing purposes.

1.33 "**Claim Notice**" has the meaning set forth in Section 12.7.

1.34 "**Clinical Trials**" means human clinical trials, including any Phase I Clinical Trials, Phase II Clinical Trials, Phase III Clinical Trials, Registrational Clinical Trials, post-Regulatory Approval trials or variations, combinations or subsets of such trials (for example, Phase I/II or Phase IB clinical trials).

1.35 "**Closing Date**" means (a) the Closing Date or (b) the SPA License Effective Date, as applicable, in each case ((a) or (b)), as defined in the Share Purchase Agreement.

1.36 "**Closing Time**" means immediately prior to (a) the Closing Date or (b) the SPA License Effective Date, in each case ((a) or (b)), as defined in the Share Purchase Agreement.

1.37 "**Collaboration Epigenomic Controller**" means any mRNA encoding an epigenetic editing protein that directly or indirectly regulates expression of one or more Gene(s) via epigenetic modification of an Insulated Genomic Domain that includes the Gene(s), an enhancer sequence, a promoter sequence, a coding sequence, a non-coding sequence, a CTCF-binding site, a cis regulatory element sequence, or any combination of the aforementioned elements.

1.38 "**Collaboration Epigenomic IP**" means the Collaboration Epigenomic Know-How and Collaboration Epigenomic Patents.

1.39 "**Collaboration Epigenomic Know-How**" means any Know-How, excluding Excluded Know-How, that (a) is conceived, discovered, developed, or otherwise made solely by or on behalf of any Party (or its Affiliates, independent contractors or sublicensees (including Sublicensees)) in the conduct of activities under the R&D Plan or jointly by or on behalf of any of the Parties (or their respective Affiliates, independent contractors or sublicensees (including Sublicensees)) in the conduct of activities under the R&D Plan and (b) relates to the identification, Development or process of making of Collaboration Epigenomic Controllers or any component

thereof, but does not relate to the identification, Development or process of making of any other Epigenomic Controllers or any component thereof.

1.40 "**Collaboration Epigenomic Patents**" means Patents that Cover any Collaboration Epigenomic Know-How (and no Know-How that is excluded from the Collaboration Epigenomic Know-How).

1.41 "**Combination Product**" means a Licensed Product sold in combination with a device (such combination can be a non-integral drug-device combination or cross-labelled drug device combination) or one or more other therapeutically or prophylactically active ingredient(s) that is not the IND-Enabling Candidate (in each case under express exclusion of buffers, fillers, bulking agents and diluents) whether combined in a single formulation or package, as applicable, or formulated separately but packaged under a single label approved by a Regulatory Authority and sold together for a single price.

1.42 "**Commercialization**" or "**Commercialize**" means, with respect to a product, activities directed to obtaining Pricing and Reimbursement approvals, securing and maintaining market access and reimbursement, marketing, advertising, promoting, distributing, importing, exporting, selling (and offering for sale or contracting to sell), providing product support, otherwise commercially exploiting, and conducting activities in preparation for the foregoing. "**Commercializing**," "**Commercialized**," and "**Commercialization**" shall have correlative meanings. For clarity, Commercialization does not include Development.

1.43 "**Commercially Reasonable Efforts**" means (a) with respect to a Party's obligations under this Agreement other than the obligations described in clause (b), such reasonable, diligent and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances taking into account the responsible allocation of such Party's resources under the circumstances (including any cost reimbursement under this Agreement) and (b) with respect to Novo Nordisk's obligations relating to the Development or Commercialization of the IND-Enabling Candidate and Licensed Product(s) under this Agreement, means efforts consistent with the efforts and resources commonly used in the pharmaceutical or biotechnology industry by companies of comparable size and resources as Novo Nordisk (including its Affiliates) for a product at a similar stage of research, development or commercialization having similar product characteristics at a similar stage in its development or product life, taking into account relevant factors including [***]. The RCA PM Parties (and after the Closing Date, PlatformCo) expressly understand and accept that the use of Commercially Reasonable Efforts may result in Novo Nordisk not initiating, or ceasing, Development or Commercialization of a Licensed Product in a particular country in the Territory.

1.44 "**Committee**" has the meaning set forth in Section 2.2.

1.45 "**Competing Product**" means any product (other than the Development Candidate, the IND-Enabling Candidate or a Licensed Product under this Agreement) that (a) uses the same Collaboration Epigenomic Controller included in the Epigenomic Controller-LNP Candidate or (b) is directed to: (1) (i) with respect to the Initial Program Target, the Initial Program Target; or (ii) if the Program Target is different from the Initial Program Target, the Program Target for the prevention, treatment or control of a cardiometabolic disease (including, for the avoidance of doubt, diabetes) in humans; or (2) during the Target Flexibility Period, any Backup Target or Proposed Backup Target for the prevention, treatment or control of a cardiometabolic disease (including, for the avoidance of doubt, diabetes) in humans.

1.46 "**Competitive Infringement**" means the actual, threatened, alleged, or suspected infringement by a Third Party of any Licensed Product-Specific Patent(s) or PM and NN Joint Developed Patent(s) that is or would be competitive with [***].

1.47 "**Competitive Infringement Action**" means any Action alleging Competitive Infringement of any Patent by a Third Party.

1.48 "**Confidential Information**" means (a) all trade secrets or confidential or proprietary information (including any tangible materials embodying any of the foregoing) of the disclosing Party or its Affiliates provided or disclosed to the other Party or any of its Affiliates in connection with this Agreement, (b) "**Confidential Information**" (as defined in the Prior Agreement) that was disclosed by a Party or any of its Affiliates to the other Party or any of its Affiliates under the Prior Agreement, (c) confidential information disclosed or exchanged under the [***], and (d) the terms and conditions of this Agreement, which are the Confidential Information of each Party; *provided*, *however*, that Confidential Information shall not include information that:

1.48.1 has been published by a Third Party or otherwise is or hereafter becomes publicly available by public use, publication or otherwise through no breach of this Agreement on the part of the receiving Party;

1.48.2 is in the receiving Party's or its Affiliate's possession prior to disclosure by the disclosing Party hereunder, and not through a prior disclosure by the disclosing Party or its Affiliates, without any obligation of confidentiality with respect to such information (as evidenced by the receiving Party's or such receiving Party's Affiliate's written records);

1.48.3 is subsequently received by the receiving Party from a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party under any agreement between such Third Party and the disclosing Party or otherwise; or

1.48.4 is independently developed by or for the receiving Party or its Affiliate without reference to, or use or disclosure of, the disclosing Party's Confidential Information (as evidenced by the receiving Party's or such Affiliate's written records);

provided, *further*, that Sections 1.48.2 through 1.48.4 above shall not apply to the terms and conditions of this Agreement. Notwithstanding anything to the contrary herein, confidential PlatformCo Licensed Know-How shall constitute the Confidential Information of PlatformCo.

1.49 "**Controlled**" or "**Controls**" means, with respect to any Intellectual Property right (including any Patent or Know-How), the possession of (whether by ownership or license, other than pursuant to this Agreement) the ability of a Party to assign, transfer, or grant access to, or to grant a license or sublicense of, such right as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to assign, transfer or grant another Person such access or license or sublicense. For avoidance of doubt, certain Intellectual Property rights may be deemed not to be "Controlled" by a Party for purposes of this Agreement as set forth in Section 10.10.2.

1.50 "**Controlling Party**" means the Party initiating and controlling any Action pursuant to Section 10.5.

1.51 "**Core IP**" means the Core Know-How and the Core Patents.

1.52 "**Core Know-How**" means any Know-How that Covers any Collaboration Epigenomic Controller; *provided* that, "Core Know-How" shall not include [***].

1.53 "**Core Patents**" means any Patents that Cover any Collaboration Epigenomic Controller; *provided* that, "**Core Patents**" shall not include [***].

1.54 [***].

1.55 "**Cost Responsibility Matter**" has the meaning set forth in Section 3.1.2(b).

1.56 "**Cover**", "**Covering**" or "**Covered**" means (a) with reference to a Patent, that the manufacture, use, offer for sale, sale or importation of a product or practice of a method would, absent a license thereto (or ownership thereof), infringe (i) in the case of an issued Patent, a claim of such Patent in the country in which such activity occurs or (ii) in the case of a Patent application, a claim of such Patent application were the Patent application to issue, and (b) with reference to Know-How, that the Manufacture, Development or Commercialization of a product or the practice of a method incorporates, embodies or otherwise makes use of such Know-How.

1.57 "**Criteria Achievement Matter**" has the meaning set forth in Section 2.2.7.

1.58 "**Criteria Amendment Matter**" has the meaning set forth in Section 2.2.6.

1.59 "**Data Package**" means, as applicable, the Development Candidate Data Package or IND-Enabling Data Package.

1.60 "**Deliver**" means to provide access to information either by providing a copy of such information (paper or electronic), granting access to a virtual data room containing such information or a combination of these means.

1.61 "**Delivery or Formulation Technology**" means any delivery system intended or used to deliver a therapeutic composition or product, including [***].

1.62 "**Developed Licensed Product-Specific Patents**" has the meaning set forth in Section 10.4.4(b).

1.63 "**Development**" means, with respect to a product, activities directed to Pre-Clinical Development and Clinical Trials and submissions to Regulatory Authorities prior to Regulatory Approval (including INDs and MAAs). For clarity, Development excludes Commercialization activities. When used as a verb, "**Develop**" means to engage in Development.

1.64 "**Development Candidate**" means the Epigenomic Controller-LNP Candidate that (a) is Developed under the R&D Plan and (b) (i) satisfies the Development Candidate Criteria and is designated by the JSC as the Development Candidate in accordance with Section 3.2.3 or (ii) is designated by Novo Nordisk as the Development Candidate in accordance with Section 3.2.3. As used herein, the term Development Candidate means the applicable Epigenomic Controller-LNP Candidate designated as the Development Candidate from time to time under this Agreement, it being understood that [***].

1.65 "**Development Candidate Criteria**" means the criteria set forth on Schedule 1.65, as may be amended from time-to-time by the JSC in accordance with Article 2.

1.66 "**Development Candidate Data Package**" means the data package delivered by the RCA PM Parties to the JSC with respect to an Epigenomic Controller-LNP Candidate, which shall include the content described in Schedule 1.65.

1.67 "**Development Milestone Event**" has the meaning set forth in Section 8.3.

1.68 "**Development Milestone Payment**" has the meaning set forth in Section 8.3.

1.69 "**Discontinued Epigenomic Controller**" means a Collaboration Epigenomic Controller that is eliminated from the Program pursuant to Section 3.2.3 or 3.3.1.

1.70 "**Discontinued Epigenomic Controller-LNP Candidate**" means an Epigenomic Controller-LNP Candidate that is eliminated from the Program pursuant to Section 3.2.3 or 3.3.1.

1.71 "**Discontinued Program Tissue LNP**" means a Program Tissue LNP that is eliminated from the Program pursuant to Section 3.2.4 or 3.3.1.

1.72 "**Discontinued Target**" means a Program Target that is replaced with a Backup Target pursuant to Section 3.3.1.

1.73 "**Disputes**" has the meaning set forth in Section 14.1.

1.74 "**Distracted Restricted Party**" has the meaning set forth in Section 6.2.1.

1.75 "**Divest**" means, with respect to a Competing Product, the sale, exclusive license or other complete transfer by the applicable Party and its Affiliates of all of their Development, Manufacturing, Commercialization and other Exploitation rights with respect to such Competing Product to a Third Party without the retention or reservation of any Development, Manufacturing, Commercialization or other Exploitation obligation, interest or participation rights (other than solely an economic interest or the right to enforce customary terms and conditions contained in the relevant agreements effectuating such transaction).

1.76 "**Dollars**" or "**US$**" means United States dollars.

1.77 "**Effective Date**" has the meaning set forth in the preamble.

1.78 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.79 "**Epigenomic Controller**" means any agent, including a polypeptide, a peptide, a nucleic acid (e.g., RNA or DNA, including both modified and unmodified forms of RNA and DNA), a nucleic acid encoded polypeptide, a gene expression modifying molecule, an epigenetic editing molecule, or a non-biologic organic molecule (i.e., a "small molecule"), that, in each case, directly or indirectly regulates expression of one or more Gene(s) via epigenetic modification of an Insulated Genomic Domain that includes the Gene(s), an enhancer sequence, a promoter sequence, a coding sequence, a non-coding sequence, a CTCF-binding site, a cis regulatory element sequence, or any combination of the aforementioned elements.

1.80 "**Epigenomic Controller-LNP Candidate**" means a Collaboration Epigenomic Controller optimized under the R&D Plan that: (a) directly or indirectly regulates the expression of the Program Target; and (b) is encapsulated within a Program Tissue LNP.

1.81 "**Equity Financing**" means, with respect to a Party, any issuance or sale of securities of such Party with the sole purpose of raising capital for working capital and operations, none of the proceeds of which would be distributed or paid to such Party's equity owners.

1.82 "**Excluded Know-How**" means Know-How [***].

1.83 "**Executive Officer**" means, for PM SpinCo, the chief executive officer or president of PM SpinCo, or his or her designee, for PlatformCo, the chief executive officer or president of PlatformCo, or his or her designee, and for Novo Nordisk, the chief executive officer or president of Novo Nordisk, or his or her designee. A Party may change its Executive Officer upon written notice to the other Parties; *provided* that such replacement individual has decision-making authority on behalf of such Party in respect of this Agreement.

1.84 "**Exploit**" means, collectively, to Develop, Manufacture and Commercialize, including to have Developed, to have Manufactured, to have Commercialized, and otherwise to commercially exploit. "**Exploitation**" has a correlative meaning.

1.85 " **FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended, and any rules, regulations, and requirements promulgated thereunder.

1.86 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.87 "**Field**" means the targeting of the Program Target for the prevention, treatment or control of a cardiometabolic disease (including, for the avoidance of doubt, diabetes) in humans.

1.88 "**Field LNP Product**" means any product for use in the Field (other than a Licensed Product under this Agreement) that contains the same Program Tissue LNP component of the IND-Enabling Candidate or Licensed Product, except that a "Field LNP Product" shall not include any product that contains a Program Tissue LNP if such Program Tissue LNP is [***].

1.89 "**Filing Acceptance**" means the written notification by the FDA or equivalent Regulatory Authority for a country in the Territory that a MAA has been accepted for filing pursuant to 21 C.F.R. §314.101 for drugs or 21 C.F.R. §601.2 for biologics or the foreign equivalent if such filing is outside the U.S.

1.90 "**First Commercial Sale**" means with respect to a Licensed Product in any country in the Territory, the first sale for monetary value of such Licensed Product in such country for use or consumption by the end user of such Licensed Product in such country after all Regulatory Approvals for such Licensed Product have been obtained in such country. The following shall not constitute a First Commercial Sale: (a) any sale of such Licensed Product to an Affiliate or Sublicensee unless such Affiliate or Sublicensee is the end user thereof; (b) any sale of such Licensed Product for use in Clinical Trials or Pre-Clinical Development activities with respect to such Licensed Product by or on behalf of a Party or, with respect to Novo Nordisk, by or on behalf of Novo Nordisk, its Affiliates or Sublicensees; or (c) any disposal or transfer of such Licensed Product for a *bona fide* charitable purpose or samples of such Licensed Product. Notwithstanding

the foregoing, sales prior to receipt of Regulatory Approval for a Licensed Product such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales" shall not be considered a First Commercial Sale.

1.91 "**First Reimbursed Sale**" means with respect to a Licensed Product and a country, the First Commercial Sale following Pricing and Reimbursement Approval for such Licensed Product in such country.

1.92 "**Flagship Affiliate**" means FSP or an Affiliate of FSP, other than PM SpinCo and its Subsidiaries, PlatformCo and its Subsidiaries, Shareholder and its Subsidiaries, and PMCo and its Subsidiaries.

1.93 [***].

1.94 "**FPIV**" means Flagship Pioneering Innovations V, Inc.

1.95 "**FPIV License**" means that certain License Agreement, effective as of March 12, 2019 between FPIV and PlatformCo, [***].

1.96 "**FPIV Patent Rights**" means the Patents licensed to PlatformCo under the FPIV License.

1.97 "**FSP**" means Flagship Pioneering, Inc., a Delaware corporation.

1.98 "**FTE**" means the equivalent of a full-time individual's work, performed by one or more individuals, at [***], carried out by an appropriately qualified employee of PlatformCo or its Affiliates, PM SpinCo or its Affiliates or Flagship Labs, LLC performing activities on behalf of PM SpinCo pursuant to the R&D Plan or this Agreement.

1.99 "**FTE Costs**" means the FTE Rate multiplied by the applicable number of FTEs who perform a specified activity pursuant to the R&D Plan. FTE Costs shall be pro-rated on a daily basis if necessary (e.g., for any Calendar Year during the Research Term that is less than a full year). Out-of-Pocket Costs, including payments to contract personnel, consultants, or subcontractors (other than to Flagship Labs, LLC), are not FTE Costs.

1.100 "**FTE Rate**" means [***], which rate shall be adjusted on January 1st of each Calendar Year during the Research Term by an amount equal to [***]. The FTE Rate represents the fully loaded rate (including all direct and indirect costs) per FTE and includes (a) all wages and salaries, office supplies, benefits, bonuses, and other general incidental expenses, and (b) direct and indirect allocations, including in connection with all direct finance, legal or other administrative labor FTEs required to support the R&D Activities and indirect overhead, general and administrative, human resources, legal and finance expenses.

1.101 "**Gene**" means DNA identified by its ENSEMBL GENE ID number.

1.102 "**General PlatformCo Licensed Patents**" means any and all PlatformCo Licensed Patents that are not Licensed Product-Specific Patents.

1.103 "**General PM SpinCo Licensed Patents**" means any and all PM SpinCo Licensed Patents that are not Licensed Product-Specific Patents.

1.104 "**Generic/Biosimilar Product**" means, with respect to a Licensed Product and on a country-by-country basis, any pharmaceutical or biological product that: (a) is sold by a Third Party (that is not a Sublicensee of Novo Nordisk or its Affiliates) under an MAA approved by a Regulatory Authority; and (b) either (i) receives Regulatory Approval in such country in reliance, in whole or in part, on the prior Regulatory Approval (or on safety or efficacy data for drug products or purity, potency and safety data for biologic products submitted in support of the prior approval) of such Licensed Product, including any product authorized for sale (A) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FD&C Act (21 U.S.C. § 355(b)(2) and 21 U.S.C. § 355(j), respectively), or Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) (including both biosimilar and interchangeable biosimilar products), (B) in the EU pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision) or (C) in any other country or jurisdiction pursuant to any equivalent of such provisions, or (ii) is otherwise substitutable under Applicable Laws for such Licensed Product at the point of dispensing without the intervention of a physician or other health care provider with prescribing authority.

1.105 "**Good Clinical Practices**" or "**GCP**" means the then-current good clinical practice standards, requirements and procedures for Clinical Trials promulgated or endorsed by the FDA, including FDA guidance and the FDA regulations set forth in 21 C.F.R. Parts 11, 50, 54, 56, and 312, and all comparable regulatory guidelines promulgated by the EMA, the ICH, and other Regulatory Authorities, as applicable.

1.106 "**Good Laboratory Practices**" or "**GLP**" means the then-current good laboratory practice standards, requirements and procedures for non-clinical studies promulgated or endorsed by the FDA, including FDA guidance and the FDA regulations set forth in 21 C.F.R. Part 58, and all comparable regulatory guidelines promulgated by the EMA, the ICH and other Regulatory Authorities, as applicable.

1.107 "**Good Manufacturing Practices**" or "**GMP**" means the then-current good manufacturing practices standards, requirements and procedures required by the FDA, as set forth in the FD&C Act and Public Health Service Act and the guidance and regulations promulgated thereunder, including the FDA regulations set forth in 21 C.F.R. Parts 210, 211, and 600-680, and

comparable laws or regulations or guidelines promulgated by the EMA, the ICH and other Regulatory Authorities, as applicable.

1.108 "**Governmental Authority**" means any federal, state, local or foreign government or municipality or subdivision thereof, and any authority, department, commission, board, bureau, agency, court, arbitrator, tribunal or instrumentality, or any applicable self-regulatory organization (including a stock exchange) exercising the powers of government. For clarity, any Regulatory Authority is a Governmental Authority.

1.109 [***].

1.110 "**Grantback IP**" has the meaning set forth in Section 13.3.3(d).

1.111 "**Grantback Product**" has the meaning set forth in Section 13.3.3(b).

1.112 "**ICH**" means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

1.113 "**IFRS**" has the meaning set forth in the definition of "Accounting Standards."

1.114 "**In Vitro Proof of Concept Criteria**" means the criteria set forth on Schedule 1.114.

1.115 "**In Vitro Proof of Concept Matter**" has the meaning set forth in Section 2.2.4.

1.116 "**IND Application**" or "**IND**" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, including any amendments or supplements thereto, or (b) the equivalent application to a Regulatory Authority in any other regulatory jurisdiction, which must be in effect to initiate or conduct clinical testing of a pharmaceutical or biological product in humans in such jurisdiction, including any amendments or supplements thereto.

1.117 "**IND-Enabling Candidate**" means: (a) if the IND-Enabling Tox Studies have been completed prior to the expiration of the Research Term, the Development Candidate that meets the IND-Enabling Criteria; (b) if the IND-Enabling Tox Studies have not been completed prior to the expiration of the Research Term, the Development Candidate as it exists as of the date of expiration of the Research Term; (c) the Development Candidate that is otherwise designated by Novo Nordisk as the IND-Enabling Candidate in accordance with Section 3.2.4; or (d) the [***].

1.118 "**IND-Enabling Criteria**" means the criteria for the pre-clinical data and other information generated under the Program that would be deemed reasonably required (by an individual with expertise in such requirements) to meet the requirements for filing an IND for the

Licensed Product with the FDA, or an analogous application to a Regulatory Authority outside of the U.S., which criteria are set forth on Schedule 1.118 as may be amended from time-to-time by the JSC in accordance with Article 2 to meet the requirements for filing an IND for the Licensed Product with the FDA.

1.119 "**IND-Enabling Data Package**" means the data package delivered by the RCA PM Parties pursuant to Section 3.2.1, which shall include the content described in Schedule 1.118.

1.120 "**IND-Enabling Tox Studies**" means studies that are designed to meet the IND-Enabling Criteria, including ADME (absorption, distribution, metabolism, and excretion) and GLP toxicology studies, studies required for the preparation of the CMC (chemistry, manufacturing, and controls) section of such IND, including studies relating to analytical methods and purity analysis, and formulation and Manufacturing development studies.

1.121 "**Indemnified Party**" has the meaning set forth in Section 12.7.

1.122 "**Indemnifying Party**" has the meaning set forth in Section 12.7.

1.123 "**Indication**" means any separate and distinct human disease, syndrome or medical condition that a Licensed Product that is approved by a Regulatory Authority is intended to diagnose, treat, prevent or ameliorate. For clarity, (a) a new formulation, dose, or delivery device for the Licensed Product, and pediatric use of the Licensed Product, shall not be considered separate Indications and (b) a label update or expansion to the existing Licensed Product label shall not be considered a new Indication, unless either change described in (a) or (b) reflects the use of the Licensed Product for a separate and distinct human disease, syndrome or medical condition. For example, treating diabetes of either type is separate and distinct from treating obesity, whereas a label update expanding the patient population from BMI greater than twenty-five (25) to greater than twenty (20) for treating obesity is not separate and distinct.

1.124 "**Information Request**" has the meaning set forth in Section 3.2.2.

1.125 "**Infringement Claim**" has the meaning set forth in Section 10.6.

1.126 "**Initial Backup Target Studies**" means the computational assessment R&D Activities to be performed by PlatformCo as set forth in the R&D Plan.

1.127 "**Initial Backup Target Studies Data Package**" means the content to be included in the data package delivered by the RCA PM Parties to the JRC for determining the feasibility of targeting Backup Targets for up- or down-regulation using PlatformCo technology, which shall consist of the content from the computational assessments described on Schedule 1.127.

1.128 "**Initial Program Studies**" means the R&D Activities to be conducted by PlatformCo and PM SpinCo to determine whether the Initial Program Target has met the In Vitro Proof of Concept Criteria.

1.129 "**Initial Program Target**" means the Gene that [***].

1.130 "**Insulated Genomic Domain**" means a continuous segment of a chromosome that (a) is bounded on both ends by a CTCF-binding site, and (b) contains one or more Genes whose expression is regulated by chromosomal regulatory elements, including enhancers, promoters, repressors, and flanking sequences of the CTCF, that lie between the CTCF-binding sites and is insulated from regulation by chromosomal regulatory elements that lie beyond the CTCF-binding site boundaries on the chromosome.

1.131 "**Intellectual Property**" means any and all of the following in any jurisdiction throughout the world and all rights associated therewith: (a) Patents; (b) trademarks and service marks, trade dress, trade names, logos, slogans, Internet domain names, corporate names, doing business designations, and all other indicia of origin, and all registrations, applications for registration and renewals of the foregoing, and all goodwill associated with the foregoing; (c) works of authorship (whether or not copyrightable), copyrights and registrations, applications for registration, and renewals thereof, including moral rights of authors and all designs, data, databases and database rights; (d) Know-How, any indicia of ownership of an invention, and any other confidential and proprietary information; (e) software (including source code, executable code, systems, network tools, data, databases, applications, firmware and all related documentation); (f) all other intellectual property and proprietary rights, and all rights associated therewith; (g) all registrations and applications for registration for any of the foregoing recognized by any Governmental Authority; and (h) all copies and tangible embodiments of any of the foregoing (in whatever form or medium).

1.132 "**Invalidity Claim**" has the meaning set forth in Section 10.5.8.

1.133 "**Joint Patents**" means the PM and NN Joint Developed Patents, the RCA PM Parties Joint Developed Patents and the LNP Joint Patents.

1.134 "**JPC**" has the meaning set forth in Section 10.11.

1.135 "**JPC Evaluated Patents**" has the meaning set forth in Section 10.11.

1.136 "**JRC**" has the meaning set forth in Section 2.1.

1.137 "**JSC**" has the meaning set forth in Section 2.2.

1.138 "**Know-How**" means all commercial, technical, scientific and other data, results, know-how and information, trade secrets, inventions, discoveries, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, knowledge, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications (including biological, chemical, pharmacological, toxicological, clinical, safety, assay, study designs and protocol and related know-how and trade secrets, and manufacturing data, pre-clinical and clinical data, the specifications of ingredients, the manufacturing processes, formulation, specifications, sourcing information, quality control and testing procedures and related know-how and trade secrets), in all cases, whether or not confidential, proprietary, patented or patentable, in written, electronic or any other form now known or hereafter developed.

1.139 "**Knowledge of PlatformCo**" (and like terms, including "**Known**" by PlatformCo) means, with respect to PlatformCo, the actual knowledge of the individuals listed on Schedule 1.139 and any successors to such individuals' positions, as well as [***].

1.140 "**Knowledge of PM Entity**" (and like terms, including "**Known**" by a PM Entity) means: (a) with respect to Pioneering Medicines, PMCo and Shareholder, the actual knowledge of PM Management [***], (b) with respect to PlatformCo, the Knowledge of PlatformCo and (c) with respect to PM SpinCo, the Knowledge of PM SpinCo.

1.141 "**Knowledge of PM SpinCo**" (and like terms, including "**Known**" by PM SpinCo) means, with respect to PM SpinCo prior to the Closing Date, the actual knowledge of PM Management [***].

1.142 "**Known Third Party Core Know-How**" means any Core Know-How that is Known as of the Effective Date by a PM Entity to be Controlled by a Third Party other than a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries.

1.143 "**Known Third Party Core Patents**" means any Core Patents that are Known as of the Effective Date by a PM Entity to be Controlled by a Third Party other than a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries.

1.144 "**Licensed Epigenomic Controller Patents**" means (a) Collaboration Epigenomic Patents and (b) any other PlatformCo Licensed Patents that [***] to the identification, Development, use of and process of making Collaboration Epigenomic Controllers or any component thereof; except that Licensed Epigenomic Controller Patents do not include [***]. For clarity, the Whitehead Patent Rights and the FPIV Patent Rights are Licensed Epigenomic Controller Patents under this Agreement.

1.145 "**Licensed IP**" means the PlatformCo Licensed IP and the PM SpinCo Licensed IP.

1.146 "**Licensed Know-How**" means (a) prior to the Closing Date, the PlatformCo Licensed Know-How and the PM SpinCo Licensed Know-How and (b) following the Closing Date, the PlatformCo Licensed Know-How.

1.147 "**Licensed Patents**" means (a) prior to the Closing Date, the PlatformCo Licensed Patents and the PM SpinCo Licensed Patents and (b) following the Closing Date, the PlatformCo Licensed Patents.

1.148 "**Licensed Product**" means a human, therapeutic product that includes as an active ingredient (whether alone or in combination with one (1) or more other active ingredients) the IND-Enabling Candidate, as the same may be modified in accordance with this Agreement. Licensed Product includes Combination Products; *provided* that this Agreement shall not be interpreted to grant a license to any proprietary active ingredient or proprietary device other than the IND-Enabling Candidate.

1.149 "**Licensed Product-Specific Patents**" means, other than Licensed Epigenomic Controller Patents, any and all Licensed Patents that Cover at least one (1) Licensed Product, or the Program Epigenomic Controller or Program Tissue LNP component thereof. Without limiting the generality of the foregoing, Licensed Product-Specific Patents shall include the Background Licensed Product-Specific Patents and Developed Licensed Product-Specific Patents.

1.150 "**LNP**" means a lipid nanoparticle.

1.151 "**LNP Joint IP**" means the LNP Joint Know-How and LNP Joint Patents.

1.152 "**LNP Joint Know-How**" means any Know-How that (a) is conceived, discovered, developed, or otherwise made solely by or on behalf of any Party (or its Affiliates, independent contractors or sublicensees (including Sublicensees)) in the conduct of activities under the R&D Plan or jointly by or on behalf of any of the Parties (or their respective Affiliates, independent contractors or sublicensees (including Sublicensees)) in the conduct of activities under the R&D Plan and (b) relates to [***].

1.153 "**LNP Joint Patents**" means Patents that Cover any LNP Joint Know-How.

1.154 " **Losses**" means damages, losses, liabilities, costs (including costs of investigation and defense), fines, penalties, expenses, or amounts paid in settlement (in each case, including reasonable attorneys' and experts' fees and expenses), in each case resulting from an Action.

1.155 "**MAA**" or "**Marketing Authorization Application**" means an application to a Regulatory Authority for approval to market a biopharmaceutical product in the respective country or group of countries, as defined in the Applicable Laws, including a New Drug Application ("**NDA**") submitted under Section 505 of the FD&C Act, a Biologics License Application

("**BLA**") submitted under Section 351(a) of the PHSA, or an analogous application or submission filed with a Regulatory Authority in a country or group of countries outside the United States to obtain approval (but excluding Pricing and Reimbursement Approval) to market such product in that country or in that group of countries.

1.156 "**Major European Countries**" means any of the following countries: United Kingdom, France, Italy, Spain and Germany.

1.157 " **Manufacturing**" means activities directed to sourcing of necessary raw materials, receipt, handling, producing, processing, packaging, labeling, filling, finishing, assembling, holding (including storage), quality assurance and quality control testing and release, and shipping of an active ingredient, biopharmaceutical product or any component thereof. For clarity, manufacturing process development and formulation development shall be considered Development activities. When used as a verb, "**Manufacture**" means to engage in Manufacturing.

1.158 " **Materials**" means all biological materials, chemical compounds and other materials provided by the Supplying Party to the Receiving Party for use by the Receiving Party to conduct the Receiving Party's R&D Activities in accordance with the R&D Plan.

1.159 "**Milestone Events**" means the Development Milestone Events and the Sales Milestone Events.

1.160 "**Milestone Payments**" means the Development Milestone Payments and the Sales Milestone Payments.

1.161 "**NDA**" has the meaning set forth in the definition of MAA.

1.162 "**Negotiation Period**" has the meaning set forth in Section 15.5.2(a).

1.163 "**Net Sales**" with respect to a Licensed Product shall be calculated in the same manner as [***], recognized in accordance with [***] applied on a consistent basis, invoiced from the sale of the Licensed Product by Novo Nordisk or its Affiliates or its Sublicensees to Third Parties (including to distributors), less the following deductions:

(a) [***]

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

(g) [***]; and

(h) [***].

Net Sales shall not include sales to Affiliates or Sublicensees, solely to the extent that such Affiliate or Sublicensee purchasing the Licensed Product intends to resell such Licensed Product to a Third Party. However, subsequent sales of Licensed Product by Novo Nordisk Affiliates or Sublicensees to a Third Party (including to a distributer) shall be included in Net Sales when sold in the market for end-user use.

Further, Net Sales shall not include the selling price of a device (as defined in Section 201(h)(1) of the FD&C Act, that is not Delivery or Formulation Technology) if the device is sold separately from the Licensed Product (i.e., not sold as a Combination Product) in that country.

For Net Sales of a Licensed Product sold as a Combination Product, the Net Sales of such a Combination Product in a country shall be determined by multiplying the Net Sales of such Combination Product by the fraction of A/(A+B), where A is the average unit selling price of the Licensed Product sold separately in that country and B is the total average unit selling price of the device or other pharmaceutical product(s), when sold separately in that country. If the Licensed Product or the device or other pharmaceutical product(s) included in the Combination Product are not sold separately, then the Parties shall negotiate in good faith the relative value of the Licensed Product, on the one hand, or the device or other pharmaceutical product(s), on the other hand (including but not limited to the purchase price and the Parties' applicable device or other pharmaceutical product(s) development costs, milestones and royalties relating to the device or other pharmaceutical product(s)) and shall determine the Net Sales of the Licensed Product contained in the Combination Product based on such allocation of value. In the event that the Parties do not initially agree on the Combination Product percentage referenced above, Royalty Payments on Net Sales shall initially be paid based on the average selling price of the Combination Product, subject to later adjustment determined through the dispute resolution process set forth in Article 14.

Net Sales in the Territory shall be calculated and reported in Dollars. With respect to Net Sales invoiced in a currency other than Dollars, (x) the rate of exchange to be used in computing the currency equivalent in Dollars of Net Sales used to determine the achievement of the Sales Milestone Payments shall be the Calendar Yearly average exchange rate between each currency of origin and Dollars, and (y) the rate of exchange to be used in computing the currency equivalent in Dollars for Royalty Payments shall be the Calendar Quarterly average exchange rate between each currency of origin and Dollars, and in either case ((x) or (y)), shall be based on the exchange rate mechanism generally applied by [***], *provided* that such mechanism is in compliance with

[***] and is the same methodology as [***] uses in preparing its audited financial reports to shareholders, consistently applied throughout the organization.

1.164 "**New In-License**" has the meaning set forth in Section 10.10.2(a).

1.165 "**New Included Patents**" means any Patent Controlled by PlatformCo or any of its Subsidiaries after the Program Handoff Date that claims an invention that was invented using or that otherwise discloses (a) Novo Nordisk Confidential Information or (b) data disclosed to PlatformCo by or on behalf of Novo Nordisk under this Agreement.

1.166 "**New PlatformCo Patents**" means, other than New Included Patents, Collaboration Epigenomic Patents and Joint Patents, any Patent Controlled by PlatformCo or any of its Subsidiaries after the Program Handoff Date that claim an invention that was invented by or on behalf of PlatformCo or any of its Subsidiaries [***] for the Exploitation of the IND-Enabling Candidate or Licensed Products in the Field in the Territory pursuant to this Agreement.

1.167 "**NN Background Improvements**" has the meaning set forth in Section 10.3.5(c).

1.168 "**NN Flagship Known Third Party Core IP**" means the NN Flagship Known Third Party Core Know-How and the NN Flagship Known Third Party Core Patents.

1.169 "**NN Flagship Known Third Party Core Know-How**" means any (a) Core Know-How that is in-licensed by Novo Nordisk or any of its Affiliates or Sublicensees from a Third Party that is a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, and (b) Known Third Party Core Know-How that is in-licensed by Novo Nordisk or any of its Affiliates or Sublicensees from a Third Party other than a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries in accordance with Section 10.10.2(b)(iii), in case of (a) and (b), after the Effective Date during the Term.

1.170 "**NN Flagship Known Third Party Core Patents**" means any (a) Core Patents that are in-licensed by Novo Nordisk or any of its Affiliates or Sublicensees from a Third Party that is a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, and (b) Known Third Party Core Patents that are in-licensed by Novo Nordisk or any of its Affiliates or Sublicensees from a Third Party other than a Third Party that is a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries in accordance with Section 10.10.2(b)(iii), in case of (a) and (b), after the Effective Date during the Term.

1.171 "**NN Originated LNP**" means an LNP that is used by the Parties in the performance of the Parties' R&D Activities under the R&D Plan and that is [***].

1.172 "**NN Unknown Third Party Core IP**" means the NN Unknown Third Party Core Know-How and the NN Unknown Third Party Core Patents.

1.173 "**NN Unknown Third Party Core Know-How**" means any Unknown Third Party Core Know-How that is in-licensed by Novo Nordisk or any of its Affiliates or Sublicensees from a Third Party in accordance with Section 10.10.2(b)(iii), other than a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, after the Effective Date during the Term.

1.174 "**NN Unknown Third Party Core Patents**" means any Unknown Third Party Core Patents that are in-licensed by Novo Nordisk or any of its Affiliates or Sublicensees from a Third Party in accordance with Section 10.10.2(b)(iii), other than a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, after the Effective Date during the Term.

1.175 "**Notice of Exercise Date**" has the meaning set forth in the Option Agreement.

1.176 "**Notice Period**" has the meaning set forth in Section 15.5.2(a).

1.177 "**Novo Nordisk**" has the meaning set forth in the preamble.

1.178 "**Novo Nordisk Collaboration Background IP**" means any Background IP Controlled by Novo Nordisk and (a) disclosed by Novo Nordisk to the RCA PM Parties for use in connection with the activities conducted under the R&D Plan or (b) actually used by Novo Nordisk in the conduct of activities under the R&D Plan; [***].

1.179 "**Novo Nordisk Developed IP**" has the meaning set forth in Section 10.3.2.

1.180 "**Novo Nordisk Developed Know-How**" has the meaning set forth in Section 10.3.2.

1.181 "**Novo Nordisk Developed Patents**" has the meaning set forth in Section 10.3.2.

1.182 "**Novo Nordisk Indemnitees**" has the meaning set forth in Section 12.1.

1.183 "**Novo Nordisk Know-How**" means any Know-How Controlled by Novo Nordisk or any of its Affiliates as of the Effective Date or thereafter during the Research Term, in each case, that Novo Nordisk discloses or makes available to an RCA PM Party (in its sole discretion) and that is necessary for the RCA PM Parties to conduct the R&D Activities delegated to the RCA PM Parties under the R&D Plan.

1.184 "**Novo Nordisk Patents**" means any Patents Controlled by Novo Nordisk or any of its Affiliates as of the Effective Date or thereafter during the Research Term, in each case, that are necessary for the RCA PM Parties to conduct the R&D Activities delegated to the RCA PM Parties under the R&D Plan.

1.185 "**Option**" has the meaning set forth in the Recitals.

1.186 "**Option Agreement**" has the meaning set forth in the Recitals.

1.187 "**Option Exercise Period**" has the meaning set forth in the Option Agreement.

1.188 "**Option Termination Date**" has the meaning set forth in the Option Agreement.

1.189 "**Other New IP**" means any Third Party Patent or Know-How that is in-licensed by a Party during the Term and is not Core IP.

1.190 "**Other New PM Party IP**" means the Other New PM Party Know-How and the Other New PM Party Patents.

1.191 "**Other New PM Party Know-How**" means any Licensed Know-How constituting Other New IP.

1.192 "**Other New PM Party Patents**" means any Licensed Patents constituting Other New IP.

1.193 "**Out-of-Pocket Costs**" means actual out-of-pocket costs and expenses paid by a Party to Third Parties in the conduct of R&D Activities under the R&D Plan, including lab supplies and consumables. Out-of-Pocket Costs exclude all overhead and office supplies for the applicable RCA PM Party to perform the R&D Activities delegated to it under the R&D Plan.

1.194 "**Party**" or "**Parties**" has the meaning set forth in the preamble.

1.195 "**Patent Challenge**" means a legal or administrative proceeding challenging the patentability, enforceability or validity of (a) if brought prior to the Closing Date, any PM SpinCo Licensed Patent or PlatformCo Licensed Patent or (b) if brought following the Closing Date, any PlatformCo Licensed Patent.

1.196 "**Patent Challenging Party**" has the meaning set forth in Section 13.2.6(a).

1.197 "**Patents**" means (a) all patents and patent applications (provisional and non-provisional) anywhere in the world, (b) all divisionals, continuations, continuations in-part thereof, or any other patent application claiming priority, or entitled to claim priority, directly or indirectly to (i) any such patents or patent applications or (ii) any patent or patent application from which such patents or patent applications claim, or is entitled to claim, direct or indirect priority, and (c) all patents issuing on any of the foregoing anywhere in the world, together with all registrations, reissues, re-examinations, patents of addition, utility models or designs, renewals, supplemental protection certificates, or extensions of any of the foregoing and counterparts thereof anywhere in the world.

1.198 "**Payment Claim**" means, with respect to the IND-Enabling Candidate or a Licensed Product in a country, (a) a Valid Claim of a Payment Patent that Covers the composition of matter or method of use of the IND-Enabling Candidate or such Licensed Product in such country or (b) a Valid Claim of a [***].

1.199 "**Payment Patents**" means collectively: [***].

1.200 "**Payment Reduction Floor**" has the meaning set forth in Section 8.5.4(d).

1.201 "**Permitted Overage**" has the meaning set forth Section 3.1.2.

1.202 "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association or other entity.

1.203 "**Phase I Clinical Trial**" means a human clinical trial of a product in the United States, the principal purpose of which is to determine metabolism, pharmacokinetic properties and clinical pharmacology actions in humans, the side effects associated with increasing doses and, if possible, to gain early evidence of effectiveness, as described in 21 C.F.R. § 312.21(a), or any comparable trial under Applicable Laws in any country or group of countries outside of the United States.

1.204 "**Phase II Clinical Trial**" means a human clinical trial of a product in the United States, the principal purpose of which is a preliminary determination of efficacy and safety either alone or in combination with other agents in a well-defined population of patients and evaluation of a range of doses, dose response, and duration of effect, as described in 21 C.F.R. § 312.21(b), or any comparable trial under Applicable Laws in any country or group of countries outside the United States.

1.205 "**Phase III Clinical Trial**" means a human clinical trial of a product in the United States that is intended to establish that the product is safe and efficacious for its intended use, define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and support labeling and Regulatory Approval for such product, as described in 21 C.F.R. § 312.21(c), or any comparable trial under Applicable Laws in any country or group of countries outside the United States.

1.206 "**Pioneering Medicines**" means the business unit within FSP identified as Pioneering Medicines.

1.207 "**PlatformCo**" has the meaning set forth in the preamble.

1.208 "**PlatformCo Background Improvements**" has the meaning set forth in Section 10.3.5(d).

1.209 "**PlatformCo CMC Activities**" means those certain CMC (chemistry, manufacturing, and controls) and other Manufacturing activities assigned to PlatformCo under the then-current R&D Plan with respect to [***], in all cases, conducted at laboratory (i.e., non-clinical) scale.

1.210 "**PlatformCo Existing Patents**" has the meaning set forth in Section 9.2.1.

1.211 "**PlatformCo In-Licensed Known Third Party Core IP**" means any Known Third Party Core Know-How or Known Third Party Core Patents that are Controlled by PlatformCo or its Subsidiaries through an in-license from a Third Party, other than a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, as of the Effective Date or thereafter during the Term.

1.212 "**PlatformCo In-Licensed Unknown Third Party Core IP**" means any Unknown Third Party Core Know-How or Unknown Third Party Core Patents that are Controlled by PlatformCo or its Subsidiaries through an in-license from a Third Party, other than a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, as of the Effective Date or thereafter during the Term.

1.213 "**PlatformCo Indemnitees**" has the meaning set forth in Section 12.1.

1.214 "**PlatformCo IP**" means all PlatformCo Existing Patents and all PlatformCo Licensed Know-How.

1.215 "**PlatformCo Licensed IP**" means the PlatformCo Licensed Know-How and the PlatformCo Licensed Patents.

1.216 "**PlatformCo Licensed Know-How**" means any and all Know-How Controlled by PlatformCo or any of its Subsidiaries as of the Effective Date or thereafter during the Term, in each case, that is [***] for the conduct of R&D Activities or the Exploitation of the IND-Enabling Candidate or Licensed Products in the Field in the Territory pursuant to this Agreement. Without limiting the generality of the foregoing, PlatformCo Licensed Know-How shall include any Collaboration Epigenomic Know-How and Core Know-How Controlled by PlatformCo or any of its Subsidiaries as of the Effective Date or thereafter during the Term and PlatformCo's interest in the RCA PM Parties Joint Developed Know-How, the PM and NN Joint Developed Know-How and the LNP Joint Know-How.

1.217 "**PlatformCo Licensed Patents**" means any and all (a) Patents that are Controlled by PlatformCo or any of its Subsidiaries as of the Effective Date, including the Patents listed on Schedule 1.217, and (b) Patents Controlled by PlatformCo or any of its Subsidiaries after the Effective Date or thereafter during the Term, in each case ((a) and (b)) that [***] for the conduct of R&D Activities or the Exploitation of the IND-Enabling Candidate or Licensed Products in the

Field in the Territory pursuant to this Agreement. Without limiting the generality of the foregoing, PlatformCo Licensed Patents shall include any (x) New Included Patents, (y) Collaboration Epigenomic Patents and Core Patents Controlled by PlatformCo or any of its Subsidiaries as of the Effective Date or thereafter during the Term and (y) PlatformCo's interest in the RCA PM Parties Joint Developed Patents, the PM and NN Joint Developed Patents and the LNP Joint Patents, and (z) Patents that are Controlled by PlatformCo or any of its Subsidiaries as of the Effective Date that are listed on Schedule 10.3.5(d) that become [***] for the conduct of R&D Activities or the Exploitation of the IND-Enabling Candidate or Licensed Products in the Field in the Territory pursuant to this Agreement after the Effective Date. Notwithstanding anything in the foregoing, following notification by PlatformCo of the issuance thereof, PlatformCo Licensed Patents excludes [***].

1.218 "**PM and NN Joint Developed IP**" has the meaning set forth in Section 10.3.3. For the avoidance of doubt, PM and NN Joint Developed IP excludes Collaboration Epigenomic IP.

1.219 "**PM and NN Joint Developed Know-How**" has the meaning set forth in Section 10.3.3. For the avoidance of doubt, PM and NN Joint Developed Know-How excludes Collaboration Epigenomic Know-How.

1.220 "**PM and NN Joint Developed Patents**" has the meaning set forth in Section 10.3.3. For the avoidance of doubt, PM and NN Joint Developed Patents excludes Collaboration Epigenomic Patents.

1.221 " **PM Entity**" means: (a) prior to the Closing Date, Pioneering Medicines, PMCo and its Subsidiaries, Shareholder and its Subsidiaries, PlatformCo and its Subsidiaries and PM SpinCo and its Subsidiaries; and (b) following the Closing Date, Pioneering Medicines, PMCo and its Subsidiaries, Shareholder and its Subsidiaries and PlatformCo and its Subsidiaries. For the avoidance of doubt, Flagship Affiliates are not PM Entities.

1.222 "**PM Management**" means the president of Pioneering Medicines, together with his or her direct reports. PM Management as of the Effective Date are identified on Schedule 1.222, which schedule may be amended from time to time by Shareholder upon written notice to Novo Nordisk. PM Management shall include any successors to such individuals' positions.

1.223 "**PM SpinCo**" has the meaning set forth in the preamble.

1.224 "**PM SpinCo Existing Patents**" has the meaning set forth in Section 9.3.1.

1.225 "**PM SpinCo Indemnitees**" has the meaning set forth in Section 12.2.

1.226 "**PM SpinCo IP**" means all PM SpinCo Existing Patents and PM SpinCo Licensed Know-How.

1.227 "**PM SpinCo Licensed IP**" means the PM SpinCo Licensed Know-How and the PM SpinCo Licensed Patents.

1.228 "**PM SpinCo Licensed Know-How**" means any Know-How Controlled by PM SpinCo or any of its Subsidiaries as of the Effective Date or thereafter during the Term prior to the Closing Date, in each case, that is [***] for the conduct of R&D Activities or the Exploitation of the IND-Enabling Candidate or Licensed Products in the Field in the Territory pursuant to this Agreement. Without limiting the generality of the foregoing, PM SpinCo Licensed Know-How shall include any Core Know-How Controlled by PM SpinCo or any of its Subsidiaries as of the Effective Date or thereafter during the Term prior to the Closing Date, and PM SpinCo's interest in the RCA PM Parties Joint Developed Know-How, the PM and NN Joint Developed Know-How and the LNP Joint Know-How.

1.229 "**PM SpinCo Licensed Patents**" means any and all (a) Patents that are Controlled by PM SpinCo or any of its Subsidiaries as of the Effective Date, including the Patents listed on Schedule 1.229, and (b) Patents Controlled by PM SpinCo or any of its Subsidiaries after the Effective Date or thereafter during the Term prior to the Closing Date, in each case ((a) and (b)) that are [***] for the conduct of the R&D Activities or the Exploitation of the IND-Enabling Candidate or Licensed Products in the Field in the Territory pursuant to this Agreement. Without limiting the generality of the foregoing, PM SpinCo Licensed Patents shall include any Core Patents Controlled by PM SpinCo or any of its Subsidiaries as of the Effective Date or thereafter during the Term prior to the Closing Date, and PM SpinCo's interest in the RCA PM Parties Joint Developed Patents, the PM and NN Joint Developed Patents and the LNP Joint Patents.

1.230 "**PMCo**" has the meaning set forth in the preamble.

1.231 "**Pre-Clinical Development**" means activities relating to the discovery and non-clinical development of a compound, product or diagnostic product, including toxicology, pharmacology, identification, characterization, modification, optimization, test method development and stability testing, formulation development, and delivery system development, but excluding Clinical Trials and Commercialization activities. When used as a verb, "**Pre-Clinically Develop**" means to engage in Pre-Clinical Development.

1.232 "**Press Releases**" has the meaning set forth in Section 11.2.2.

1.233 "**Pricing and Reimbursement Approval**" means, with respect to a Licensed Product, (a) in any regulatory jurisdiction where a Regulatory Authority or other Third Party authorizes reimbursement for, or approves or determines pricing for, biopharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective,

publication) of reimbursement authorization or pricing approval or determination (as the case may be) for such Licensed Product in such regulatory jurisdiction, or (b) in the United States, [***].

1.234 "**Prior Agreement**" means that certain Collaboration Agreement between PM (NN) Explorations, Inc. and Novo Nordisk, dated May 5, 2022.

1.235 "**Program**" means all research, discovery and Development activities undertaken by or on behalf of the Parties for the purpose of discovering and Developing the IND-Enabling Candidate pursuant to the then-current R&D Plan and such other activities as the Parties may agree in writing.

1.236 "**Program Epigenomic Controller**" has the meaning set forth in Section 3.2.3.

1.237 "**Program Handoff Date**" means [***].

1.238 "**Program Target**" means the Target in the Program Tissue identified in the then-current R&D Plan.

1.239 "**Program Tissue**" means adipose tissue.

1.240 "**Program Tissue LNP**" means an LNP for delivery of a Collaboration Epigenomic Controller into the Program Tissue.

1.241 "**[***]**" means any LNP Joint Patents that, [***].

1.242 "**Project Leader**" has the meaning set forth in Section 2.7.

1.243 "**Project Team**" has the meaning set forth in Section 2.7.

1.244 "**Proposed Backup Targets**" means each of the Target(s) set forth on Schedule 1.244 as may be amended pursuant to Section 3.3.2.

1.245 "**Proposed Terms**" has the meaning set forth in Schedule 13.3.3(d).

1.246 "**Prosecution and Maintenance**" or "**Prosecute and Maintain**" means, with regard to a Patent, the preparation, filing, prosecution and maintenance (including payment of any patent annuity fees) of such Patent, as well as re-examinations, reissues, appeals, post grant reviews (PGR), inter partes reviews (IPR) and requests for patent term adjustments and patent term extensions with respect to such Patent, together with the initiation or defense of interferences, positions and other similar proceedings with respect to the particular Patent, and any appeals therefrom. For clarification, "**Prosecution and Maintenance**" or "**Prosecute and Maintain**" shall not include any other enforcement actions taken with respect to a Patent.

1.247 "**R&D Activities**" has the meaning set forth in Section 3.1.1.

1.248 "**R&D Budget**" has the meaning set forth in Section 3.1.1.

1.249 "**R&D Budget Report**" has the meaning set forth in Section 8.2.2.

1.250 "**R&D Costs**" means the FTE Costs (at the then-current FTE Rate) and the Out-of-Pocket Costs (without markup) incurred by or on behalf of a Party in the conduct of the R&D Activities under the R&D Plan.

1.251 "**R&D Expert**" has the meaning set forth in Schedule 2.4.

1.252 "**R&D Plan**" has the meaning set forth in Section 3.1.1.

1.253 "**RCA PM Parties Joint Developed IP**" has the meaning set forth in Section 10.3.1. For the avoidance of doubt, RCA PM Parties Joint Developed IP excludes Collaboration Epigenomic IP.

1.254 "**RCA PM Parties Joint Developed Know-How**" has the meaning set forth in Section 10.3.1. For the avoidance of doubt, RCA PM Parties Joint Developed Know-How excludes Collaboration Epigenomic Know-How.

1.255 "**RCA PM Parties Joint Developed Patents**" has the meaning set forth in Section 10.3.1. For the avoidance of doubt, RCA PM Parties Joint Developed Patents excludes Collaboration Epigenomic Patents.

1.256 "**RCA PM Party**" or "**RCA PM Parties**" has the meaning set forth in the preamble.

1.257 "**RCA PM Party At-Fault Matter**" has the meaning set forth in Section 3.1.2(b).

1.258 "**Receiving Party**" has the meaning set forth in Section 3.8.1.

1.259 [***].

1.260 "**Registrational Clinical Trial**" means a Clinical Trial of a Licensed Product that is designed: (a) to establish that the Licensed Product is safe and effective for its intended use; (b) to determine warnings, precautions, and adverse reactions that are associated with the Licensed Product in the intended dosage range and dose duration to be prescribed; (c) to provide an adequate basis for physician labeling; and (d) to support the submission of an MAA to seek Regulatory Approval. For clarity, a Registrational Trial may be a separate Clinical Trial or a portion of a Clinical Trial that combines two phases (e.g., the Phase III portion of a Phase II/III Clinical Trial).

1.261 "**Regulatory Approval**" means any approval, clearance, authorization, registration, certification, license or permit granted by any Regulatory Authority and necessary to commercially manufacture, import, export, market and sell a Licensed Product in the applicable jurisdiction in accordance with Applicable Laws, including any BLAs, NDAs and other MAAs, but excluding Pricing and Reimbursement Approval.

1.262 "**Regulatory Authority**" means any national, supranational, regional, state or local Governmental Authority, including the FDA or the EMA, with responsibility for regulating Development, Manufacturing, and Commercialization activities, including granting any Regulatory Approvals, with respect to a pharmaceutical or biological product in the applicable jurisdiction.

1.263 [***].

1.264 "**Regulatory Exclusivity**" means, with respect to each Licensed Product in any country or jurisdiction in the Territory, (a) orphan drug exclusivity as described, as of the Effective Date, in 21 U.S.C. § 360cc, (b) reference product exclusivity as described, as of the Effective Date, in 42 U.S.C. § 262(k)(7) or (c) new chemical entity exclusivity as described, as of the Effective Date, in 21 U.S.C. § 355(c)(3)(E) and 21 U.S.C. § 355(j)(5)(F), and any equivalent exclusivity in any country or jurisdiction outside the United States.

1.265 "**Regulatory Materials**" means, with respect to a Licensed Product, (a) all INDs, NDAs, BLAs, applications to and correspondence with a Regulatory Authority for special designation or status (e.g., fast-track designation) or expedited review (e.g., priority review) and all other similar filings (including counterparts of any of the foregoing in any country in the Territory), (b) any applications for Regulatory Approval and other applications, filings, dossiers, or similar documents (e.g., pediatric investigation plans) submitted to a Regulatory Authority in any country for the purpose of obtaining Regulatory Approval from that Regulatory Authority, (c) all supplements and amendments to any of the foregoing, (d) all data, including clinical data, and other information contained in, and Regulatory Authority correspondence relating to, any of the foregoing and (e) any other materials relating to interactions (whether oral or written) with any Regulatory Authority regarding the safety, efficacy, Regulatory Approval, Development, testing, investigation, labeling, packaging, manufacturing, fabrication, storage, marketing, promotion, sale, Commercialization, shipment, import, export, sale or distribution of the Licensed Product.

1.266 "**Rejection Notice**" has the meaning set forth in the Option Agreement.

1.267 "**Replacement Criteria**" has the meaning set forth in Section 3.3.1.

1.268 "**Replacement Criteria Matter**" has the meaning set forth in Section 2.2.5.

1.269 "**Replacement Plans**" has the meaning set forth in Section 3.3.1.

1.270 "**Replacement Plans Matter**" has the meaning set forth in Section 2.2.5.

1.271 "**Representatives**" has the meaning set forth in Section 11.1.2.

1.272 "**Required Whitehead Reports**" has the meaning set forth in Section 15.5.2(a).

1.273 "**Research Term**" means the period commencing on the Effective Date and ending on the earlier of: (a) completion of the R&D Activities assigned to the Parties under the R&D Plan; and (b) [***] after the Effective Date (clause (b), the "**Base Term**"); *provided*, *however*, that (i) if the R&D Activities set forth in the R&D Plan have not been completed by the end of the Base Term, then, upon the written request of Novo Nordisk on or prior to the end of such Base Term, the Research Term shall automatically extend for an additional [***] period (the "**Extended Base Term**") and (ii) if the Initial Program Target is replaced with a Backup Target in accordance with Section 3.3 and if the R&D Activities set forth in the R&D Plan have not been completed by the end of the Extended Base Term, then, upon the written request of Novo Nordisk on or prior to the end of such Extended Base Term, the Research Term shall automatically extend for an additional [***] period.

1.274 "**Research Term Amounts Paid**" has the meaning set forth in Section 8.2.3.

1.275 "**Research Term Incurred Costs**" has the meaning set forth in Section 8.2.3.

1.276 "**Residual Information**" has the meaning set forth in Section 11.5.

1.277 "**Restricted Parties**" has the meaning set forth in Section 6.1.3.

1.278 "**Revenue Assignment**" has the meaning set forth in Section 15.5.2.

1.279 "**Revenue Buyer**" has the meaning set forth in Section 15.5.2.

1.280 "**Revenue Buyout**" has the meaning set forth in Section 15.5.2(a).

1.281 "**Revenue Buyout Notice**" has the meaning set forth in Section 15.5.2(a).

1.282 "**Review Period**" has the meaning set forth in Section 3.2.2.

1.283 "**Royalty Payment**" has the meaning set forth in Section 8.5.2.

1.284 "**Royalty Rates**" has the meaning set forth in Section 8.5.1.

1.285 "**Royalty Term**" has the meaning set forth in Section 8.5.2.

1.286 "**Sales Milestone Event**" has the meaning set forth in Section 8.4.

1.287 "**Sales Milestone Payment**" has the meaning set forth in Section 8.4.

1.288 "**Service Provider**" means a Third Party engaged by Novo Nordisk or its Affiliates to perform Development, Manufacturing or Commercialization activities on Novo Nordisk's behalf, including without limitation a clinical research organization, contract manufacturing organization, distributor, subcontractor, consultant or any other service provider.

1.289 "**Share Purchase Agreement**" means the share purchase agreement in the form attached as Exhibit A to the Option Agreement.

1.290 "**Shareholder**" has the meaning set forth in the preamble.

1.291 "**SPA License Effective Date**" has the meaning set forth in the Share Purchase Agreement.

1.292 "**Subject Shares**" has the meaning set forth in the Option Agreement.

1.293 "**Sublicense**" means a grant of rights from Novo Nordisk or its Affiliate to a Third Party under any of the rights licensed to Novo Nordisk by PlatformCo or PM SpinCo under Section 5.2.

1.294 "**Sublicensee**" means a Third Party to which Novo Nordisk or its Affiliates has granted or grants rights, as permitted under this Agreement, to Develop, Manufacture or Commercialize the IND-Enabling Candidate or the Licensed Products, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights), but shall not include any Service Provider solely in its capacity as Service Provider.

1.295 "**Subsequent R&D Budget Matter**" has the meaning set forth in Section 2.2.3.

1.296 "**Subsidiary**" means, with respect to any Party, any entity, corporation or other organization, of which such Party, directly or indirectly (i) owns more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under Applicable Laws; *provided*, *however*, that such ownership interest provides actual control over such Person), (ii) is a general partner, or (iii) possesses the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

1.297 "**Supplying Party**" has the meaning set forth in Section 3.8.1.

1.298 "**Target**" means any specific Gene.

1.299 "**Target Flexibility Period**" means the period commencing on the Effective Date and ending on the earlier of [***].

1.300 "**Target Replacement**" has the meaning set forth in Section 3.3.1.

1.301 "**Term**" has the meaning set forth in Section 13.1.

1.302 "**Territory**" means all countries of the world.

1.303 "**Third Party**" means any Person other than (a) PM SpinCo and its Subsidiaries, (b) PlatformCo and its Subsidiaries and (c) Novo Nordisk and its Affiliates.

1.304 "**Third Party Claim**" has the meaning set forth in Section 12.7.

1.305 "**Third Party Losses**" means Losses resulting from an Action by a Third Party.

1.306 "**Third Party Wind-down Costs**" has the meaning set forth in Section 3.1.2(b).

1.307 "**Trademarks**" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

1.308 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.309 "**Unknown Third Party Core Know-How**" means any Core Know-How that is not Known, as of the Effective Date, by a PM Entity to be Controlled by a Third Party. Unknown Third Party Core Know-How excludes Know-How constituting Affiliate Core IP.

1.310 "**Unknown Third Party Core Patents**" means any Core Patents that are not Known, as of the Effective Date, by a PM Entity to be Controlled by a Third Party. Unknown Third Party Core Patents excludes Affiliate Core Patents.

1.311 "**Upstream License Costs**" has the meaning set forth in Section 10.10.1.

1.312 "**Upstream Licenses**" means any and all agreements between PlatformCo or any of its Affiliates, on the one hand, and any Third Party, on the other hand, pursuant to which PlatformCo has in-licensed (or has an option to in-license), or will in-license (or obtain an option to in-license) during the Term, any Patents or Know-How Controlled by such Third Party that are included as part of the PlatformCo Licensed Patents or PlatformCo Licensed Know-How, as applicable. Schedule 1.312 sets forth a list of all Upstream Licenses as of the Effective Date.

1.313 "**Upstream Licensor**" means a Third Party that is party to an Upstream License.

1.314 "**US GAAP**" has the meaning set forth in the definition of Accounting Standards.

1.315 "**Valid Claim**" means, on a country-by-country basis, a claim of (a) any issued and unexpired Patent that has not been (i) held permanently invalid or unenforceable by a decision of a court or governmental body of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed, (ii) disclaimed or rendered unenforceable through disclaimer or otherwise, (iii) abandoned, or (iv) permanently lost through a post grant challenge or opposition proceeding without any right of appeal or review; and (b) any pending patent application for a Patent that has not been (i) abandoned or (ii) finally rejected without the possibility of appeal or refiling, or without such appeal having been taken or refiling having been made within the applicable time periods; *provided*, *however*, that if such patent application is pending for more than [***] after the earliest filing date from which the patent application claims priority, such claim shall not constitute a Valid Claim unless and until a Patent therefrom issues with such claim (from and after which time the same would be deemed a Valid Claim).

1.316 "**Whitehead**" means Whitehead Institute for Biomedical Research.

1.317 "**Whitehead Indemnitee**" has the meaning set forth in Section 12.14.

1.318 "**Whitehead Licenses**" means that certain Patent License Agreement between Whitehead and PlatformCo, dated May 22, 2019 (the "**Exclusive Whitehead License**"), and that certain Patent License Agreement (co-exclusive) between Whitehead and PlatformCo, dated May 22, 2019 (the "**Co-Exclusive Whitehead License**").

1.319 "**Whitehead Patent Rights**" means the Patents licensed to PlatformCo under any Whitehead License.

2. GOVERNANCE.

2.1 **JRC**. Within [***] after the Effective Date, the Parties shall establish a joint research committee (the "**JRC**"), which shall have the responsibility and authority to:

2.1.1 oversee the conduct of the Project Team and the progress of the Program under the R&D Plan;

2.1.2 provide guidance on overall strategy, priorities and decisions for the Program;

2.1.3 serve as a forum for exchanging information and facilitating discussions regarding the conduct of the Program;

2.1.4 propose any changes to the then current R&D Plan or the R&D Budget to the JSC;

2.1.5 prepare the R&D Budget and R&D Plan for Calendar Year 2025 and any subsequent Calendar Year during the Research Term for review and approval by the JSC;

2.1.6 in the event the Initial Program Target is replaced in accordance with Section 3.3.1, propose the Replacement Plans and Replacement Criteria for the new Program Target to the JSC;

2.1.7 propose any changes to the Development Candidate Criteria or the IND-Enabling Criteria to the JSC;

2.1.8 oversee the preparation of the Development Candidate Data Package and IND-Enabling Candidate Data Package;

2.1.9 discuss progress reports and other information generated by the Parties in performing the R&D Activities;

2.1.10 discuss the Initial Program Studies Data Package and make a recommendation to the JSC as to whether the Initial Program Target met the In Vitro Proof of Concept Criteria;

2.1.11 discuss any R&D Activities that the Parties anticipate will not be completed by the end of the Research Term, consider whether such activities should be undertaken, and propose any necessary amendments to the R&D Plan and R&D Budget in light thereof; and

2.1.12 encourage and facilitate cooperation and communication among the Parties with respect to the Program.

2.2 **JSC**. Within [***] after the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**" and, together with the JRC, the "**Committees**" and each a "**Committee**"), which shall have the responsibility and authority to:

2.2.1 work to achieve business alignment among the Parties with respect to the Program;

2.2.2 review and approve any amendments to the R&D Plan or R&D Budget proposed by the JRC;

2.2.3 approve the R&D Budget ("**Subsequent R&D Budget Matter**") and R&D Plan for Calendar Year 2025 and any subsequent Calendar Year during the Research Term;

2.2.4 determine whether the Initial Program Target met the In Vitro Proof of Concept Criteria (an "**In Vitro Proof of Concept Matter**");

2.2.5 review and approve the Replacement Plans (a "**Replacement Plans Matter**") and Replacement Criteria (a "**Replacement Criteria Matter**") for the new Program Target proposed by the JRC;

2.2.6 review and approve any changes to the Development Candidate Criteria or the IND-Enabling Criteria proposed by the JRC (each a "**Criteria Amendment Matter**");

2.2.7 evaluate and determine whether the Development Candidate Criteria and IND-Enabling Criteria have been achieved or are likely to be achieved (each a "**Criteria Achievement Matter**");

2.2.8 resolve any disputes of the JRC; and

2.2.9 perform such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be agreed upon by the Parties in writing from time to time.

2.3 **Membership; Meetings**. The JRC shall be composed of six (6) members, with each Party designating two (2) of its employees or consultants with appropriate seniority and functional expertise as members of the JRC. The JSC shall be composed of nine (9) members, with each Party designating three (3) of its employees or consultants with appropriate seniority and functional expertise as members of the JSC. Each Committee shall be chaired by one (1) of the members of each Committee (the "**Chairperson**"). Appointment of the Chairperson shall rotate among the Parties every (12) months during the Research Term. The initial Chairperson shall be a representative of [***], followed by [***], and then [***]. The JRC shall meet, in person, by teleconference or by video-teleconference, at least monthly, or on a schedule as unanimously agreed by the JRC members. The JSC shall meet, in person, by teleconference or by video-teleconference, at least two (2) times per Calendar Year, or more often as unanimously agreed by the JSC members. A member of any Committee may reasonably call a meeting of the applicable Committee upon no less than [***] notice, *provided* that, unless agreed by the Parties, the JSC shall not be required to meet more than six (6) times per Calendar Year. If any matter to be decided by a Committee requires prompt attention to enable scientific progress then, notwithstanding the number of meetings such Committee has held to date, such Committee shall use reasonable efforts to hold a meeting to address such matter as promptly as practicable or may act by written consent (including by e-mail) if agreed by the Parties. In-person meetings shall be at a location unanimously agreed upon by the Committee members. Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to its Committee members' participation in Committee meetings. The first meeting of each Committee shall be within [***] after the first designation of members of such Committee. Any member of a Committee may designate a substitute of appropriate seniority and functional expertise to attend meeting of the applicable Committee with prior written notice to the Committee members of the other Parties. Ad hoc guests who are subject to written confidentiality obligations commensurate in scope to the provisions in Article 11 may be invited to Committee meetings by agreement of

the Committee members. Each Party may replace its Committee members at any time, upon written notice to the other Parties.

2.4 **Decision-Making; Limitations**.

2.4.1 **In General**. The members of each Committee shall act in good faith to cooperate with one another and seek agreement and consensus with respect to issues to be decided by such Committee. Decisions of each Committee shall be made by [***], with the Novo Nordisk members collectively having one (1) vote, the PM SpinCo members collectively having one (1) vote and the PlatformCo members collectively having one (1) vote. The presence of at least one (1) Committee member representing each Party shall constitute a quorum in order for decisions to be made. The Committee shall have only such powers as are specifically delegated to it in this Article 2, and such powers shall be subject to the terms and conditions set forth herein.

2.4.2 **JRC**. If the JRC is unable to reach a [***] decision on a matter that is within its decision-making authority within [***] after it has met and attempted to reach such decision, then the matter shall be referred to the JSC.

2.4.3 **JSC**. If the JSC is unable to reach a [***] decision on a matter that is within its decision-making authority within [***] after it has met and attempted to reach such decision, then the matter shall be referred to the Executive Officers of the Parties, who shall use reasonable efforts to reach agreement on such matters. If such Executive Officers of the Parties are unable to reach [***] with respect to a particular matter within [***] after the matter is first referred to such Executive Officers, then, except with respect to a disputed Criteria Amendment Matter, disputed Criteria Achievement Matter, disputed Replacement Plans Matter or disputed Subsequent R&D Budget Matter, [***] shall have the right to make the final decision with respect to the relevant matter, including with respect to a disputed Replacement Criteria Matter or a disputed In Vitro Proof of Concept Matter; *provided* that (a) [***] shall take into reasonable consideration the recommendations and concerns raised by [***], (b) [***] shall make such decisions in good faith using reasonable business judgment, which shall not be unreasonably delayed and (c) [***] shall not have the right to (i.e., consensus between Novo Nordisk and the applicable RCA PM Party shall be required): [***]. In the event the Executive Officers of the Parties are unable to reach [***]: (A) with respect to a disputed [***], no Party shall have final decision-making authority with respect to such disputed matter, and such [***] must be mutually agreed to by the Parties, except that [***] shall have final decision-making authority with respect to a disputed Replacement Criteria Matter as set forth above; and (B) with respect to any disputed [***], no Party shall have final decision-making authority with respect to such disputed matter and such Criteria Achievement Matter shall be resolved in accordance with the dispute resolution provision set forth in Schedule 2.4, *provided* that nothing in clause (B) of this sentence shall limit Section 3.2.3 or Section 3.2.4. Without limiting the generality of the foregoing, no representative of any [***]. The Research Term shall be extended during the pendency of any good faith dispute as to a Criteria Amendment Matter, Criteria Achievement Matter or Replacement Plans Matter, up to

an aggregate maximum of [***] for all such disputes; *provided, however*, that the maximum extension pursuant to this Section 2.4.3 and Section 3.1.2(b) shall not exceed [***] in the aggregate.

2.5 **Agenda; Minutes**. The Chairperson or the Chairperson's delegate shall be responsible for: (a) preparing Committee meeting agendas reasonably in advance of Committee meetings, which Committee meeting agendas shall include all agenda items reasonably requested by any Committee member for inclusion therein; (b) sending invitations and a Committee meeting agenda along with appropriate information for such agenda to all members of the Committee at least [***] before the next scheduled meeting of the Committee; and (c) preparing and circulating minutes within [***] after each meeting of the Committee setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions, or determinations approved by the Committee. Such minutes shall be effective only after being approved by both Parties. Definitive minutes of all Committee meetings shall be finalized no later than [***] after the meeting to which the minutes pertain.

2.6 **Subcommittees**. From time-to-time, each Committee may establish subcommittees to oversee particular projects or activities within the scope of authority of such Committee, as it deems necessary or advisable. Each subcommittee shall consist of an equal number of members from each Party, in such number as the applicable Committee determines is appropriate from time-to-time and shall meet with such frequency as the JSC shall determine. All decisions of each subcommittee shall be made by unanimous decision, with each Party's designated subcommittee members having collectively one (1) vote in all decisions. If, with respect to a matter that is subject to a subcommittee's decision-making authority, the subcommittee cannot reach unanimity, the matter shall be referred to the applicable Committee for resolution.

2.7 **Project Team**. Within [***] after the Effective Date, the RCA PM Parties shall form a single integrated project team to manage and coordinate the conduct of the R&D Plan by the RCA PM Parties, which shall consist of at least two (2) representatives from each of PM SpinCo and PlatformCo, each with experience relevant to the applicable Party's responsibilities under the R&D Plan (such program team, the "**Project Team**"). PM SpinCo shall designate one of its representatives as the project leader ("**Project Leader**") to oversee, manage and coordinate the R&D Activities to be conducted by the RCA PM Parties under the R&D Plan and shall make decisions in line with the R&D Plan at the direction of the Project Team. The Project Leader shall report to the JRC. The Project Team shall meet, in person, by teleconference or by video-teleconference, at least monthly, or on a schedule as unanimously agreed by the Project Team. Each RCA PM Party commits to providing to the Project Team all experimental methods, data, results and information, pertaining to the conduct of the R&D Plan, in a transparent manner, on an ongoing and as needed basis in order to enable effective management, interpretation, and decision-making of the R&D Activities by the RCA PM Parties; *provided, however*, that, without limiting Section 5.6, nothing herein shall require PlatformCo to disclose to the Project Team any

Know-How with respect to the design, optimization, Development or Manufacturing of Epigenomic Controllers or any component thereof. PM SpinCo and PlatformCo may each replace any of its Project Team representatives upon prior notice to the other. Neither the Project Team nor the Project Leader may amend, modify or waive compliance with any term or condition of this Agreement.

2.8 **Alliance Managers**. Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (each, an "**Alliance Manager**") (who may be a member of any Committee). Each Alliance Manager shall thereafter be permitted to attend Committee meetings as a nonvoting observer (if not a member), subject to the confidentiality provisions of Article 11. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate communication regarding all activities hereunder. The Alliance Managers shall lead the communications among the Parties and shall be responsible for following up on decisions made by a Committee. The name and contact information for such Alliance Manager, as well as any replacement(s) chosen by PM SpinCo, PlatformCo or Novo Nordisk, in their sole discretion, from time-to-time, shall be promptly provided to the other Parties in accordance with Section 15.6. The Alliance Managers may not amend, modify or waive compliance with any term or condition of this Agreement.

2.9 **Discontinuation of the Committees; Discontinuation of the Project Team**. The Committees and any subcommittees shall automatically discontinue three (3) months after the expiration of the Research Term, except for the JPC, which shall discontinue in accordance with Section 10.11. Thereafter, the Committees shall have no further obligations under this Agreement and each Party shall designate a contact person for the exchange of information under this Agreement. The Project Team shall automatically discontinue on the Closing Date, and thereafter the Project Team shall have no further obligations under this Agreement.

3. PROGRAM.

3.1 Program Research and Development Activities.

3.1.1 R&D Plan and R&D Budget.

(a) During the Research Term, the Parties will engage in a collaborative effort to identify and conduct Pre-Clinical Development with respect to Epigenomic Controller-LNP Candidates in accordance with the R&D Plan and R&D Budget. The agreed research and Development activities (the "**R&D Activities**") to be undertaken by the Parties shall be set forth in the research and development plan (the "**R&D Plan**") with associated budgets for each of PM SpinCo and PlatformCo (collectively, the "**R&D Budget**"), with the initial R&D Plan and R&D Budget for Calendar Years 2023 and 2024 attached hereto as Schedule 3.1.1. The R&D Budget and each amendment thereto shall be reasonably calculated to fund the applicable R&D Activities under the R&D Plan. During the Research Term, all Development by the Parties under this

Agreement shall be conducted pursuant to the R&D Plan; *provided, however*, that [***]. Without limiting any other provision of this Agreement, the Parties agree that the R&D Plan shall not require the Parties to conduct R&D Activities with respect to (i) products other than Epigenomic Controller-LNP Candidates or (ii) more than one (1) Epigenomic Controller-LNP Candidate at a time, *provided* that the R&D Plan may permit the Parties to evaluate any number of Epigenomic Controller-LNP Candidates to determine whether to advance an Epigenomic Controller-LNP Candidate as a potential Development Candidate. Each Party shall use Commercially Reasonable Efforts to perform the R&D Activities allocated to such Party in a good scientific manner and in accordance with the timelines set forth in the R&D Plan and in compliance with Applicable Laws.

(b) [***]. In addition, during the Research Term: the JRC (i)(A) shall review the R&D Plan and R&D Budget on a regular basis, and in no event less frequently than [***], and (B) following such review, may propose any amendments to the JSC; (ii) shall meet prior to [***] during the Research Term for a [***] review of the R&D Budget, at which meeting the JRC may propose any amendments to the JSC and [***]; and (iii) shall, prior to [***] beginning in [***], prepare the R&D Budget and R&D Plan for the next Calendar Year during the Research Term for the review and approval by the JSC. If the JSC approves any amendments in accordance with this Section 3.1.1(b), the JSC shall update the R&D Plan and R&D Budget accordingly; *provided*, *however*, that in no event shall the Research Term be extended in connection with the approval of such amendments (except as set forth in the definition of Research Term or in Section 3.1.2(b)). In addition, any Party may propose amendments to the R&D Plan and R&D Budget at any time during the Research Term and the JRC shall consider whether to propose such amendments to the JSC for approval; *provided*, *however*, that in no event shall the Research Term be extended in connection with the approval of such amendments (except as set forth in the definition of Research Term or in Section 3.1.2(b)). No representative of an RCA PM Party on the JSC shall unreasonably withhold, condition or delay its approval of any amendment to the R&D Budget to the extent necessary to implement [***].

(c) Prior to [***] beginning in Calendar Year 2024, the JSC shall review and approve the R&D Plan and R&D Budget for the next Calendar Year within the Research Term. If the JSC cannot agree on such R&D Plan or R&D Budget, then the RCA PM Parties shall not be required to perform any R&D Activities, other than those set forth in the current R&D Plan, until such R&D Plan or R&D Budget has been approved in accordance with Section 2.4.3.

3.1.2 **R&D Costs**.

(a) Except as set forth below, Novo Nordisk shall be solely responsible for all R&D Costs incurred by the Parties in performing the R&D Activities (in accordance with the then-current R&D Plan, the then-current R&D Budget and Section 8.2), and except with respect to Permitted Overages or as otherwise set forth in Section 3.1.2(b), Novo Nordisk shall not be required to pay more than what is set forth in the then-current R&D Budget. The RCA PM

Parties shall incur R&D Costs solely related to those R&D Activities set forth in the then-current R&D Plan. A budget overage of up to [***] of the budgeted R&D Costs set forth in the then-current R&D Budget for R&D Activities specified in the R&D Plan for any Calendar Year shall be deemed to be automatically approved by the JSC (a "Permitted Overage") and shall be borne solely by Novo Nordisk. Subject to this Section 3.1.2, each RCA PM Party shall conduct the R&D Activities allocated to such RCA PM Party in accordance with R&D Budget. Notwithstanding the foregoing, an RCA PM Party shall have no obligation to incur any R&D Costs in excess of the then-current R&D Budget (plus Permitted Overages), except as otherwise set forth in Section 3.1.2(b).

(b) (i) If the JSC approves an amendment to increase the R&D Budget for a Calendar Year in accordance with Section 2.4 (including in the event of [***]) requested by a Party, then Novo Nordisk shall be solely responsible for the resulting increase in R&D Costs in accordance with Section 3.1.2(a); (ii) if the R&D Costs for a Calendar Year exceed the then-current R&D Budget (plus Permitted Overages) for such Calendar Year other than as set forth in the foregoing clause (i) (each, a "**Cost Responsibility Matter**"), then the JSC shall meet to discuss such matter and:

(A) any R&D Costs in excess of the then-current R&D Budget (plus Permitted Overages), to the extent such excess R&D Costs resulted from: [***] (each ((1)-(5)), an "**RCA PM Party At-Fault Matter**"), such excess R&D Costs shall be borne solely by [***];

(B) the RCA PM Parties shall not be obligated to perform any R&D Activities that are Cost Responsibility Matters but not RCA PM Party At-Fault Matters unless and until the associated R&D Budget excess is approved by Novo Nordisk in accordance with Section 2.4;

(C) to the extent approved by Novo Nordisk in accordance with Section 2.4, any R&D Budget excess amounts for R&D Activities that are Cost Responsibility Matters but not RCA PM Party At-Fault Matters shall be borne solely by Novo Nordisk, and the RCA PM Parties shall thereafter continue to perform any such Cost Responsibility Matters that are not RCA PM Party At-Fault Matters in accordance with the then-current R&D Plan (as amended); and

(D) to the extent not approved by Novo Nordisk in accordance with Section 2.4; (1) the RCA PM Parties shall not be obligated to perform any R&D Activities that are Cost Responsibility Matters but not RCA PM Party At-Fault Matters and Novo Nordisk shall be solely responsible for any termination or cancellation fees or wind-down costs required to be paid under the applicable agreement with the applicable independent contractor (collectively, "**Third Party Wind-down Costs**") with respect to such R&D Activities; and (2) the

RCA PM Parties shall not be in breach of their obligations under the R&D Plan or this Agreement as a result of not performing such R&D Activities that are not RCA PM Party At-Fault Matters;

and (iii) the Research Term shall be extended during the pendency of any amendment process for the R&D Plan and for increasing the R&D Budget in accordance with Section 2.4 pursuant to the procedures set forth in this Section 3.1.2(b), up to a maximum of [***] in the aggregate for all such amendments; *provided, however*, that the maximum extension pursuant to this Section 3.1.2(b) and Section 2.4.3 shall not exceed [***] in the aggregate. If any of the terms of the R&D Plan or R&D Budget contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

3.1.3 **Reports**. Each Party shall provide the JRC with written reports or presentations summarizing the performance and results of the R&D Activities at each JRC meeting or as otherwise agreed among the Parties. Each report or presentation shall cover the R&D Activities conducted by or on behalf of such Party since the previous JRC meeting, including a summary of results, information and data generated and any R&D Activities expected to be conducted under the R&D Plan for the next Calendar Quarter. In addition, upon the reasonable request of a Party, the other Parties shall provide to such Party updates regarding the performance and results of the R&D Activities allocated to such Party under the R&D Plan and shall respond to such Party's reasonable questions or requests for additional information relating to such activities in a timely manner.

3.2 **Development Candidate Criteria and Designation; IND-Enabling Criteria and Designation**.

3.2.1 **Data Package**. The RCA PM Parties shall provide to the JSC, at least [***] prior to the applicable JSC meeting, the following: (i) the Development Candidate Data Package for a meeting where the JSC shall consider whether the Development Candidate Criteria has been met; and (ii) the IND-Enabling Data Package for a meeting where the JSC shall consider whether the IND-Enabling Criteria has been met, as applicable. The RCA PM Parties shall also provide a draft Data Package to Novo Nordisk in advance of each such Committee meeting to enable Novo Nordisk to review the contents of such Data Package and allow the Parties to discuss the contents and completeness of such Data Package in advance of such meeting. If the IND-Enabling Tox Studies have not been completed prior to the expiration of the Research Term, then the RCA PM Parties shall deliver to Novo Nordisk an IND-Enabling Data Package comprising all data and other information generated in the conduct of the R&D Activities prior to the expiration of the Research Term and that would otherwise be required to be included in the IND-Enabling Data Package.

3.2.2 **Information Request**. The JSC shall promptly (and in any event within [***] after the receipt of a Data Package) (the "**Review Period**") discuss and evaluate such Data Package and determine whether the Development Candidate Criteria or IND-Enabling Criteria, as applicable, has been achieved and provide prompt written notice of such determination to each

Party. During the Review Period, Novo Nordisk may provide an RCA PM Party with written notice requesting from such Party reasonable additional information (including, the underlying information used to create such Data Package, such as data listings, data sets and programs used for the analyses collected by such Party in the course of conducting R&D Activities pursuant to the R&D Plan) (the "**Information Request**"). Such Party shall use Commercially Reasonable Efforts to provide such information (only to the extent such information is in such Party's Control in the form in which such information is maintained by such Party) within [***] after receipt of such Information Request. The applicable Review Period shall be extended by a period corresponding to the number of days required for the applicable Party to fulfil the Information Request.

3.2.3 **Development Candidate Designation**. If the JSC determines that an Epigenomic Controller-LNP Candidate that is Developed under the R&D Plan satisfies the Development Candidate Criteria, then such Epigenomic Controller-LNP Candidate shall be the Development Candidate under this Agreement. Without limiting the foregoing, [***]. Upon designation of an Epigenomic Controller-LNP Candidate as the Development Candidate, all Collaboration Epigenomic Controllers other than the Collaboration Epigenomic Controller used in such Development Candidate (the "**Program Epigenomic Controller**") shall be deemed to be Discontinued Epigenomic Controllers. For the avoidance of doubt, at any time before designation of a Development Candidate as the IND-Enabling Candidate, the Parties may replace the Development Candidate with another Epigenomic Controller-LNP Candidate that uses the Program Epigenomic Controller and, upon such replacement, such Epigenomic Controller-LNP Candidate shall be the Development Candidate for all purposes hereunder. [***] shall have final decision making authority with respect to replacement of the Development Candidate under this Section 3.2.3.

3.2.4 **IND-Enabling Candidate Designation**. If the JSC determines that the Development Candidate satisfies the IND-Enabling Criteria, then such Development Candidate shall be the IND-Enabling Candidate under this Agreement. If the IND-Enabling Tox Studies for such Development Candidate have not been completed prior to the expiration of the Research Term, such Development Candidate as it exists as of the date of expiration of the Research Term shall be the IND-Enabling Candidate under this Agreement. Without limiting the foregoing, [***]. Upon designation of the Development Candidate as the IND-Enabling Candidate, (a) all Epigenomic Controller-LNP Candidates other than the Epigenomic Controller-LNP Candidate that was designated as the IND-Enabling Candidate shall be deemed to be Discontinued Epigenomic Controller-LNP Candidates, and (b) all Program Tissue LNP(s) other than the Program Tissue LNP used in the IND-Enabling Candidate shall be deemed to be Discontinued Program Tissue LNP(s).

3.2.5 **Initial Program Studies**. Upon completion of the Initial Program Studies, the RCA PM Parties shall deliver to the JRC the Initial Program Studies Data Package. Promptly

following delivery of the Initial Program Studies Data Package to the JRC, the JRC shall discuss the Initial Program Studies Data Package and make a recommendation to the JSC as to whether the Initial Program Target met the In Vitro Proof of Concept Criteria.

3.3 **Program Target Replacement; Identification of the Backup Target; Initial Backup Target Studies; Backup Target Validation Studies**.

3.3.1 **Target Flexibility**. During the Target Flexibility Period, Novo Nordisk shall have the right to replace the Initial Program Target with the Backup Target by written notice to the JSC. Novo Nordisk may exercise such right no more than once during the Target Flexibility Period. If Novo Nordisk timely exercises its right to replace the Initial Program Target with the Backup Target ("**Target Replacement**"), then (a) the Backup Target shall become the Program Target and (b) the Initial Program Target shall become a Discontinued Target and shall be subject to the terms and conditions set forth in Section 3.4. At any time after Target Replacement, the Parties may mutually agree to eliminate from the Program any Program Tissue LNP under consideration at the time of Target Replacement, at which time such Program Tissue LNP shall become a Discontinued Program Tissue LNP and shall be subject to Section 3.4. Promptly upon replacement of the Initial Program Target as contemplated by this Section 3.3.1, the JRC shall meet to discuss and agree upon a new R&D Plan, R&D Budget, Development Candidate Criteria and IND-Enabling Criteria for such Program Target (the new R&D Plan and new R&D Budget, collectively the "**Replacement Plans**," and the new Development Candidate Criteria and new IND-Enabling Criteria, collectively the "**Replacement Criteria**"), which shall be submitted to the JSC for approval. Unless the Parties mutually agree otherwise, the Replacement Plan shall require the replacement of any or all Collaboration Epigenomic Controllers or Epigenomic Controller-LNP Candidates previously being evaluated with respect to the Discontinued Target and, once so replaced, such Collaboration Epigenomic Controllers and Epigenomic Controller-LNP Candidates shall become Discontinued Epigenomic Controllers or Discontinued Epigenomic Controller-LNP Candidate, as applicable, and shall be subject to the terms and conditions set forth in Section 3.4. No representative of an RCA PM Party on the JRC shall unreasonably withhold, condition or delay its approval of any portion of the Replacement Plans and Replacement Criteria. If, within [***] after Target Replacement, the JSC cannot agree on any portion of the Replacement Plans submitted to it by the JRC, then any Party may refer such matter for resolution by the Executive Officers pursuant to Section 14.2. If such matter is not resolved following escalation to the Executive Officers pursuant to Section 14.2, then the mutual agreement of the Parties shall be needed to approve the Replacement Plans, *provided* that the RCA PM Parties shall not unreasonably withhold, condition or delay the approval of the Replacement Plans. If, within [***] after Target Replacement, the JSC cannot agree on any portion of the Replacement Criteria submitted to it by the JRC, then any Party may refer such matter for resolution by the Executive Officers pursuant to Section 14.2. If such matter is not resolved following escalation to the Executive Officers pursuant to Section 14.2, then Novo Nordisk shall have final decision-making authority with respect to the

disputed portion of the Replacement Criteria. Upon the expiration of the Target Flexibility Period, the Program Target may not be replaced unless mutually agreed by the Parties in writing.

3.3.2 **Backup Target**. Promptly following the Effective Date, the RCA PM Parties shall commence the Initial Backup Target Studies and Novo Nordisk shall commence the Backup Target Validation Studies, in each case for the Proposed Backup Targets. Within [***] after completion of the Initial Backup Target Studies, the RCA PM Parties shall deliver to the JRC the Initial Backup Target Studies Data Package and within [***] after completion of both the Initial Backup Target Studies and the Backup Target Validation Studies, Novo Nordisk shall deliver to the JRC the Backup Target Validation Studies Data Package along with written notice identifying one Proposed Backup Target, if any, that Novo Nordisk is electing as the Backup Target. Following receipt of such Backup Target Validation Studies Data Package and written notice, the Proposed Backup Target identified in such written notice shall become the Backup Target, and all other Proposed Backup Targets shall become Discontinued Targets and shall be subject to the terms and conditions set forth in Section 3.4. If the Backup Target Validation Studies Data Package indicates that no Proposed Backup Target meets the validation criteria established prior to commencement of the Backup Target Validation Studies, then the Parties may mutually agree in writing that the RCA PM Parties shall conduct Initial Backup Target Studies and Novo Nordisk shall conduct Backup Target Validation Studies of additional Proposed Backup Target(s) to be mutually agreed upon. With respect to any additional Proposed Backup Target(s) that are mutually agreed upon, the foregoing process for identifying one Backup Target from such additional Proposed Backup Target(s) shall apply. Novo Nordisk may remove Proposed Backup Targets by notice to the RCA PM Parties, and such removed Proposed Backup Targets shall become Discontinued Targets and shall be subject to the terms and conditions set forth in Section 3.4. Schedule 1.244 shall be amended to reflect any Proposed Backup Targets so added or removed. At the end of the Target Flexibility Period, if Novo Nordisk did not elect to replace the Initial Program Target with the Backup Target, then such Backup Target shall become a Discontinued Target subject to the terms and conditions set forth in Section 3.4.

3.4 **Discontinued Targets; Discontinued Epigenomic Controllers; Epigenomic Controller-LNP Candidate**. The following terms shall apply with respect to any Discontinued Target, Discontinued Epigenomic Controller, Discontinued Epigenomic Controller-LNP Candidate or Discontinued Program Tissue LNP following designation as such under this Agreement: (a) no Party shall have any further obligation under the R&D Plan with respect to such Discontinued Target, Discontinued Epigenomic Controller, Discontinued Epigenomic Controller-LNP Candidate or Discontinued Program Tissue LNP, as applicable, and (b) all licenses and rights granted under Sections 5.1 and 5.2 in connection with such Discontinued Target, Discontinued Epigenomic Controller, Discontinued Epigenomic Controller-LNP Candidate or Discontinued Program Tissue LNP shall immediately terminate. Effective [***], PM SpinCo (x) shall assign, and does hereby assign, to PlatformCo all of its right, title and interest in and to any Discontinued Epigenomic Controller or Discontinued Epigenomic Controller-LNP Candidate, including any and

all Patents that (i) Cover any Discontinued Epigenomic Controller but do not Cover the Program Epigenomic Controller or (ii) Cover any Discontinued Epigenomic Controller-LNP Candidate but do not Cover the IND-Enabling Candidate, in each case ((i) and (ii)), that are Controlled by PM SpinCo immediately prior to the Closing Time, and (y) shall grant, and does hereby grant, to PlatformCo or its designee, a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, with the right to grant sublicenses through multiple tiers, to use any and all Know-How Controlled by PM SpinCo immediately prior to the Closing Time that pertains to any Discontinued Target, Discontinued Epigenomic Controller and Discontinued Epigenomic Controller-LNP Candidate for any purpose.

3.5 **Records**. Each Party shall, and shall use Commercially Reasonable Efforts to require its permitted subcontractors to, maintain complete and accurate records of all Program activities performed, which records shall be maintained in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes and in accordance with Applicable Laws. Each Party shall document all R&D Activities in written records according to Applicable Laws, including national and international guidelines such as ICH, GCP, GLP and GMP. Each Party shall have the right to review such records maintained by the other Parties with respect to the Program at reasonable times, as reasonably requested by the Party obtaining access to such other Party's results. Notwithstanding the foregoing, Novo Nordisk shall not be required to disclose, and the RCA PM Parties shall not have the right to review, any records of Novo Nordisk, its Affiliates or subcontractors that relate to (a) [***], (b) Novo Nordisk's decision whether or not to exercise the Option or (c) without limiting the requirements of Section 4.1.3(b), any Development work conducted by or on behalf of Novo Nordisk from and after the Program Handoff Date. All such records, including any and all results, information or data therein, shall (x) constitute the Confidential Information of the Party maintaining and providing access to such results, and (y) not be used by the reviewing Party for any purpose other than as necessary to exercise its rights and perform its obligations under the R&D Plan or this Agreement including, with respect to Novo Nordisk, to assess the status or results of the Program or to determine whether to exercise the Option.

3.6 **Performance by Independent Contractors or Affiliates**. If agreed in the R&D Plan, a Party may contract or delegate any portion of its R&D Activities to an independent contractor (including, in the case of an RCA PM Party, Flagship Labs, LLC) or Affiliate of such Party subject to the terms and conditions of Section 15.10 and a written agreement by and between such independent contractor or Affiliate and the engaging Party that (a) enables such engaging Party to fully satisfy its obligations under this Agreement and (b) requires that the independent contractor or Affiliate comply with all applicable terms of this Agreement. Unless otherwise agreed by the Parties, the engaging Party shall include in each such independent contractor or Affiliate agreement provisions whereby the engaging Party obtains ownership of, or a fully sublicensable exclusive license under and to, any Know-How and Patents that are developed by the independent contractor or Affiliate in the performance of such agreement and are necessary for

the Development, Manufacture or Commercialization of any Development Candidate or Licensed Products Developed by such independent contractor or Affiliate; [***]. From and after the Effective Date, neither RCA PM Party shall execute any independent contractor or Affiliate agreement pursuant to which such independent contractor or Affiliate shall perform R&D Activities by or on behalf of an RCA PM Party without Novo Nordisk's prior written consent if such agreement would require the payment of Third Party Wind-down Costs to such independent contractor or Affiliate.

3.7 **Compliance with Novo Nordisk Principles for the Use of Animals**. Prior to the use of animals in connection with the R&D Plan by any RCA PM Party, such RCA PM Party shall obtain Novo Nordisk's prior written approval therefor, including with respect to facilities to be used in connection therewith. If animals are so used, the Parties agree to ensure high welfare standards for experimental animals used in any activities to be conducted pursuant to the R&D Plan. Each RCA PM Party acknowledges that it has read and understood Novo Nordisk's Principles for the Use of Animals attached hereto as Schedule 3.7 and agrees to adhere to and comply with these obligations. Each RCA PM Party shall (a) promptly notify Novo Nordisk in the event of any material unexpected issues in relation to animal welfare or bioethical concerns that occur under the R&D Plan and (b) report to Novo Nordisk the number of experimental animals used (and if applicable, planned to be used) by such RCA PM Party under the R&D Plan in a given Calendar Year (if any) no later than [***] prior to the end of such Calendar Year. The Parties agree to reasonably collaborate to address any such issues and concerns to the extent such issues and concerns relate to more than local legal requirements. Each RCA PM Party acknowledges that Novo Nordisk (i) will review the R&D Plan's anticipated animal use and the protocol(s) associated therewith and (ii) may require an on-site animal welfare inspection, in each case, prior to Novo Nordisk's approval of the initiation of any experimental animal activities to be conducted pursuant to the R&D Plan. If Novo Nordisk notifies either RCA PM Party that it wishes to perform such animal welfare inspection prior to or during the Research Term, then such RCA PM Party shall give, and shall cause its Affiliates and permitted subcontractors to give, Novo Nordisk access to the facilities in which such experimental activities will be conducted, in each case, upon reasonable notice of no less than [***]; *provided*, that any such audit shall not be conducted more than once per Calendar Year (except in the event that an audit identifies any issues, in which case Novo Nordisk shall be permitted to undertake a follow-up audit) and shall be conducted during normal business hours and in a manner intended to minimize any disruptions to such RCA PM Party's, its Affiliate's or subcontractor's day-to-day business.

3.8 **Materials Transfer**.

3.8.1 Each Party (each, a "**Supplying Party**") shall transfer to the other Party(ies) (each, a "**Receiving Party**") the Materials required to be transferred by such Supplying Party to such Receiving Party, as set forth in the R&D Plan. All such Materials shall be used by the Receiving Party in accordance with the terms and conditions of this Agreement, including the

R&D Plan, solely for the purpose of performing its R&D Activities under the R&D Plan or, with respect to Novo Nordisk, exercising its rights under this Agreement, and the Receiving Party shall not transfer such Materials to any Third Party, except to an independent contractor as provided in Section 3.6, as otherwise contemplated by this Agreement (including the R&D Plan) or upon the written consent of the Supplying Party. For clarity, this Section 3.8 will not restrict a Party from using Materials that are publicly available from a Third Party. Except for any clinical supplies of the IND-Enabling Candidate produced by the Parties under the R&D Plan, any unused Materials shall be returned to the Supplying Party (or destroyed as may be requested by the Supplying Party in writing) promptly following the end of the Research Term or earlier upon request by the Supplying Party. All Confidential Information that specifically relates to the Materials shall be Confidential Information of the Supplying Party.

3.8.2 Each Party shall not, and shall not attempt to, and shall not permit any Affiliate or a Third Party to, or attempt to, identify or determine in any way the chemical, physical or structural characteristics or identity, sequence or composition of any of the Supplying Party's Materials nor modify or make derivatives or analogs of the Supplying Party's Materials, and shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of any of the Supplying Party's Materials or analyze such Materials by physical, chemical or biochemical means, except, in each case, to the extent set forth in the R&D Plan or as necessary to conduct the R&D Plan or, with respect to Novo Nordisk, exercising its rights under this Agreement.

3.8.3 The Receiving Party shall use all Materials with prudence and appropriate caution in any experimental work, since all of their characteristics may not be known. THE MATERIALS PROVIDED UNDER THIS AGREEMENT ARE EXPERIMENTAL IN NATURE. EXCEPT AS SET FORTH IN THIS AGREEMENT, (A) SUCH MATERIALS ARE PROVIDED "AS IS," AND (B) WITH RESPECT TO SUCH MATERIALS, THE SUPPLYING PARTY (I) MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND (II) EXPRESSLY DISCLAIMS ALL SUCH WARRANTIES, INCLUDING WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

3.9 **Information Security**. Each Party will use commercially reasonable efforts to ensure that it has adequate information security that protects Confidential Information from accidental or deliberate misuse or breach, or that would publicly expose such information. Each Party will maintain reasonable information security systems with administrative, physical, organizational and technical controls sufficient to protect against material risks towards Confidential Information.

4. DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION.

4.1 **Development Diligence; Development Responsibilities**. Following the Program Handoff Date, the following terms shall apply:

4.1.1 **Development Diligence**. Novo Nordisk (directly, or with or through one or more of its Affiliates, Sublicensees or contractors) shall use Commercially Reasonable Efforts to Develop at least [***].

4.1.2 **Development Responsibilities; [***]**.

(a) Subject to the terms and conditions of this Agreement, as among the Parties, Novo Nordisk shall have the sole right, at its sole cost and expense, for managing and conducting all activities relating to the Development of the IND-Enabling Candidate and Licensed Products, including for the purpose of obtaining Regulatory Approval in the Field and in the Territory. Novo Nordisk shall conduct its Development activities in good scientific manner and in compliance with Applicable Laws. Notwithstanding anything to the contrary herein, in the event that the Program Handoff Date occurs prior to completion of the PlatformCo CMC Activities and the expiration of the Research Term, (i) [***], and (ii) such R&D Plan and such R&D Budget shall continue until the earlier of (i) completion of such PlatformCo CMC Activities or (ii) expiration of the Research Term in accordance with Section 1.273.

(b) Following [***] but prior to [***], if Novo Nordisk proposes to [***], then (i) Novo Nordisk and PlatformCo shall meet to discuss Novo Nordisk's proposal for such [***] and (ii) Novo Nordisk shall not undertake such [***] without PlatformCo's prior written consent, such consent not to be unreasonably conditioned, withheld or delayed. If Novo Nordisk and PlatformCo do not agree regarding such [***], then either such Party may refer such matter for resolution by the Executive Officers for resolution pursuant to Section 14.2. If such matter is not resolved following escalation to the Executive Officers pursuant to Section 14.2, then [***]. Following [***], Novo Nordisk shall have the right to make [***], in its sole discretion, so long as the [***] does not require any changes to the Program Epigenomic Controller [***].

4.1.3 **Development Records and Reporting**.

(a) **Records**. Novo Nordisk shall maintain complete and accurate records of all activities conducted by or on behalf of Novo Nordisk in furtherance of seeking Regulatory Approval for the Licensed Products in the Field in the Territory in accordance with Applicable Laws. Such records shall be maintained in sufficient detail and in a good scientific manner appropriate for Patent and regulatory purposes.

(b) **Reporting**. No later than January 1st of each Calendar Year prior to First Commercial Sale, Novo Nordisk shall provide PlatformCo with a written report summarizing the material Development activities it has performed, or caused to be performed, since the preceding report, its material Development activities in process, and a [***] Development timeline

anticipated for the forthcoming Calendar Year (including the categories of information set forth in Schedule 4.1.3(b)), [***]. Novo Nordisk shall respond to PlatformCo's reasonable questions or requests for additional information relating to such reports in a timely manner. Notwithstanding the foregoing, Novo Nordisk's obligations under this Section 4.1.3(b) shall terminate upon a Change of Control of PlatformCo.

4.1.4 **Regulatory Submissions and Approvals**.

(a) **Regulatory Matters**. Novo Nordisk shall have the sole right, at its sole cost and expense, to seek and attempt to obtain Regulatory Approval for the Licensed Products in the Field in the Territory.

(b) **Ownership of Regulatory Approvals**. Novo Nordisk shall own all Regulatory Materials, including all submissions and applications for Regulatory Approvals, for the Licensed Products in the Field in the Territory.

(c) **Regulatory Cooperation**. Novo Nordisk shall keep PlatformCo reasonably informed with regard to regulatory activities and shall provide to PlatformCo summary updates regarding its regulatory activities no less than once per Calendar Year. [***]. Notwithstanding the foregoing, Novo Nordisk's obligations under this Section 4.1.4(c) shall [***].

(d) **Pricing and Reimbursement Approvals**. Novo Nordisk shall have the sole right to seek and attempt to obtain Pricing and Reimbursement Approvals for the Licensed Products in the Field in the Territory. [***].

4.2 **Manufacturing**.

4.2.1 **Development Supply**. During the Research Term, the Parties shall Manufacture and have Manufactured the IND-Enabling Candidate in accordance with the R&D Plan. Without limiting the foregoing, the R&D Plan anticipates that the Parties shall jointly evaluate and select an independent contractor (subject to Section 3.6), that meets all Parties' standards and requirements, to Manufacture the IND-Enabling Candidate and PlatformCo shall execute an agreement with such independent contractor for such Manufacturing. Such agreement shall. Following the IND submission for such IND-Enabling Candidate, PlatformCo shall [***]. In addition to the foregoing, subject to the last sentence of Section 4.1.2(a), following the Program Handoff Date, Novo Nordisk shall have the right, at its sole discretion, cost and expense, to Manufacture and supply the IND-Enabling Candidate and the Licensed Products for the Development of the IND-Enabling Candidate and the Licensed Products in the Field in the Territory.

4.2.2 **Commercial Supply**. Novo Nordisk shall have the sole right, at its sole cost and expense, to Manufacture and have Manufactured the IND-Enabling Candidate and the Licensed Products for the Commercialization of the Licensed Products in the Field in the Territory.

4.3 **Commercialization**.

4.3.1 **Commercialization Diligence**. Novo Nordisk (directly, or with or through one or more of its Affiliates, Sublicensees or contractors) shall use Commercially Reasonable Efforts to Commercialize [***], in each case *provided* that such Licensed Product has obtained Regulatory Approval (including Pricing and Reimbursement Approval where required by Applicable Law). Subject to the foregoing, Novo Nordisk shall have the sole right and discretion with respect to undertaking Commercialization of the Licensed Products in the Field in the Territory, at its sole cost and expense.

4.3.2 **Reporting Obligations**. Novo Nordisk shall provide PlatformCo with written notice of the achievement of the First Commercial Sale and First Reimbursed Sale of each Licensed Product in the Field in the Territory (a) if such event occurs [***], promptly after such event becomes known to Novo Nordisk's Alliance Manager (but in no event later than [***] after such event) and (b) if such event occurs in any other country, no later than [***] after such event.

4.3.3 **Trademarks**. Novo Nordisk shall have the sole right to brand the Licensed Products in the Field in the Territory using Novo Nordisk related Trademarks and any other Trademarks and trade names it determines appropriate for the Licensed Products, which branding may vary by country. Novo Nordisk shall own all rights in such Trademarks and may register and maintain such Trademarks in the countries within the Territory, where and how it determines appropriate.

5. LICENSES; TECHNOLOGY TRANSFER.

5.1 **Program Research and Development Licenses**.

5.1.1 **Non-Exclusive License to the RCA PM Parties**. Subject to the terms and conditions of this Agreement, Novo Nordisk hereby grants to each RCA PM Party, a non-exclusive, worldwide, non-transferable (except in accordance with Section 15.5), royalty-free license, with no right to grant sublicenses, except to permitted subcontractors as provided in Section 3.6, under and to the Novo Nordisk Know-How and Novo Nordisk Patents solely to the extent necessary for such RCA PM Party to conduct its R&D Activities under the R&D Plan.

5.1.2 **Non-Exclusive License to PM SpinCo**. Subject to the terms and conditions of this Agreement, PlatformCo hereby grants to PM SpinCo, a non-exclusive, worldwide, non-transferable (except in accordance with Section 15.5), royalty-free license, with no right to grant sublicenses, except to permitted subcontractors as provided in Section 3.6, under

and to the PlatformCo Licensed IP solely to the extent necessary for PM SpinCo to conduct its R&D Activities under the R&D Plan.

5.1.3 **Non-Exclusive License to PlatformCo**. Subject to the terms and conditions of this Agreement, PM SpinCo hereby grants to PlatformCo, a non-exclusive, worldwide, non-transferable (except in accordance with Section 15.5), royalty-free license, with no right to grant sublicenses, except to permitted subcontractors as provided in Section 3.6, under and to the PM SpinCo Licensed IP solely to the extent necessary for PlatformCo to conduct its R&D Activities under the R&D Plan.

5.1.4 **Exclusive Licenses to Novo Nordisk**. Subject to the terms and conditions of this Agreement, PM SpinCo hereby grants to Novo Nordisk: (a) an exclusive (even as to PM SpinCo), worldwide, non-transferable (except in accordance with Section 15.5), royalty-free license, with no right to grant sublicenses, except to permitted subcontractors as provided in Section 3.6, under the PM SpinCo Licensed IP solely to the extent necessary for Novo Nordisk to conduct its R&D Activities under the R&D Plan; and (b) an exclusive (even as to PM SpinCo), worldwide, non-transferable (except in accordance with Section 15.5), royalty-free license, with no right to grant sublicenses, except to permitted subcontractors as provided in Section 3.6, under the PM SpinCo Licensed IP during the period between the Program Handoff Date and the Closing Date, to Develop and Manufacture the IND-Enabling Candidate and Licensed Products in the Field in the Territory.

5.2 **License to PlatformCo Licensed IP**.

5.2.1 **Grant**. Subject to the terms and conditions of this Agreement, PlatformCo hereby grants to Novo Nordisk an exclusive (even as to PlatformCo), royalty-bearing, transferable (but only in accordance with Section 15.5) license, with the right to grant sublicenses through multiple tiers of sublicensees as provided in Section 5.3, under the PlatformCo Licensed IP, to conduct its R&D Activities under the R&D Plan and to otherwise research, Develop, Manufacture, Commercialize and otherwise Exploit the IND-Enabling Candidate and Licensed Products in the Field in the Territory.

5.2.2 **Restrictive Covenants**.

(a) Novo Nordisk shall not, and shall cause its Affiliates and Sublicensees not to, [***].

(b) Other than as permitted under Section 4.1.2(b) or with PlatformCo's prior written consent, Novo Nordisk shall not, and shall cause its Affiliates and Sublicensees not to, modify, enhance, improve, optimize or otherwise derivatize the Program Epigenomic Controller.

(c) Novo Nordisk shall not, and shall cause its Affiliates and Sublicensees not to, use the Program Epigenomic Controller [***]. For the avoidance of doubt, nothing in this Section 5.2.2(c) shall serve to limit Novo Nordisk's right to practice any Joint Patents, including any RCA PM Parties Joint Patents Controlled by PM SpinCo following the Closing Date.

5.3 **Novo Nordisk's Right to Sublicense**.

5.3.1 [***]. Subject to the requirements set forth in this Section 5.3, from and after the Program Handoff Date, Novo Nordisk shall have the right to grant and authorize Sublicenses (through multiple tiers) of the rights granted to Novo Nordisk pursuant to Section 5.2 [***]. For the avoidance of doubt, nothing in this Section 5.3.1 shall serve to limit Novo Nordisk's ability to engage subcontractors as permitted by Section 3.6, including contract manufacturers to Manufacture Development supply of the IND-Enabling Candidate or Licensed Products as permitted under Section 4.2.1.

5.3.2 **Requirements of Sublicenses**. Each Sublicense granted by Novo Nordisk to a Third Party shall be in writing and shall be consistent with the terms and conditions of this Agreement. No Sublicense shall diminish, reduce or eliminate any obligation of Novo Nordisk under this Agreement. Novo Nordisk shall at all times remain fully responsible for the actions of its Sublicensees pursuant to this Agreement, including without limitation the payment of any milestones and royalties due under Article 8 below with respect to the activities of such Sublicensee. Each Sublicense shall contain the following provisions: (a) a requirement that the Sublicensee comply with all applicable terms of this Agreement, and (b) if such Sublicense contains a right to Commercialize Licensed Products, such Sublicense shall also contain the following provisions: (i) a requirement that the Sublicensee submit applicable sales or other reports to Novo Nordisk to the extent necessary or relevant for Novo Nordisk to submit the reports required to be made or records required to be maintained under this Agreement, and (ii) the right for Novo Nordisk to inspect and audit such Sublicensee's books and records for the purpose of verifying the basis and accuracy of payments made under such Sublicense to the extent attributable to rights sublicensed under this Agreement, and disclose the results of any such audit to PlatformCo, which right Novo Nordisk shall exercise on behalf and at the expense of PlatformCo upon PlatformCo's written request. [***].

5.4 **Reservation of Rights**.

5.4.1 No rights, other than those expressly set forth in this Agreement, are granted to any Party under this Agreement, and no additional rights shall be deemed granted to any Party by implication, estoppel or otherwise, with respect to any Intellectual Property rights. All rights not expressly granted by any Party or its Affiliates to another Party under this Agreement are reserved.

5.4.2 The RCA PM Parties shall retain rights under the licenses granted to Novo Nordisk in Section 5.2 to the extent [***] to conduct and have conducted any activities assigned to the RCA PM Parties pursuant to this Agreement.

5.5 **Whitehead Licenses and FPIV License**.

5.5.1 **Termination of Whitehead Licenses or FPIV License**. If a Whitehead License or the FPIV License is terminated for any reason, then: (a) PlatformCo shall promptly notify Novo Nordisk of such termination; (b) (i) in the event of termination of a Whitehead License for any reason, if Novo Nordisk is not then in default of this Agreement, Novo Nordisk may negotiate a direct license from Whitehead under the Whitehead Patent Rights pursuant to Section 2.3 of each Whitehead License (which provision PlatformCo shall not waive or permit to terminate) with rights and terms substantially equivalent to the rights and terms of such Whitehead License, including without limitation financial terms, *provided* that any non-identical terms shall be negotiated between Whitehead and Novo Nordisk in good faith under reasonable terms and conditions, and (ii) in the event of termination of the FPIV License for any reason other than by PlatformCo pursuant to Section 12.3 of the FPIV License, Novo Nordisk shall, from the effective date of such termination, automatically become a direct licensee of FPIV under the FPIV License in accordance with and pursuant to Section 13.2 of the FPIV License (which provision PlatformCo shall not waive or permit to terminate); and (c) to the extent necessary, PlatformCo shall reasonably assist Novo Nordisk in obtaining such direct license from Whitehead or FPIV, as applicable.

5.5.2 **U.S. Manufacturing**. Novo Nordisk agrees that any Licensed Products (as defined in the Whitehead Licenses) used or sold in the United States shall be manufactured substantially in the United States as required by 35 U.S.C. § 204 and 37 C.F.R. § 401 et. seq., as amended. PlatformCo shall provide reasonable assistance to Novo Nordisk to seek a waiver from any such requirement at Novo Nordisk's election.

5.5.3 **Retained Rights**.

(a) **Whitehead**. Novo Nordisk acknowledges that Whitehead retains the right to practice the Whitehead Patent Rights for research, teaching, and other educational purposes including use in third-party sponsored research. Notwithstanding anything to the contrary in this Agreement, except to the extent otherwise provided in Article 11, PlatformCo shall not disclose Novo Nordisk Confidential Information to the co-exclusive licensee under the Co-Exclusive Whitehead License.

(b) **FPIV**. Novo Nordisk acknowledges that PlatformCo has granted FPIV a non-exclusive, royalty-free, fully paid sublicensable (to Flagship Entities (as defined in the FPIV License) and service providers thereof) license to practice, and to permit Flagship Entities to practice, the FPIV Patent Rights within the Licensed Field (as defined in the FPIV License) in the Territory (as defined in the FPIV License) for non-commercial research and non-clinical

development purposes or to perform under the Managerial Agreement (as defined in the FPIV License), in each case except for the purpose of targeting the Initial Program Target, Program Target or any Proposed Backup Target for so long as such target remains an Initial Program Target, Program Target or Proposed Backup Target, as applicable, under this Agreement.

(c) **Academic and Not-For-Profit Research Institutes**. Novo Nordisk acknowledges that Whitehead retains the right to grant non-exclusive licenses to other nonprofit or academic institutions to practice the Whitehead Patent Rights for research, teaching, and other educational purposes; *provided*, *however*, that in no event shall any license permit the practice or use of any Whitehead Patent Rights in the Field (as such term is defined in the Whitehead Licenses) in the Territory (as such term is defined in the applicable Whitehead License) for commercial activities (meaning commercial development, production, manufacture, distribution or sale of products or provision of services for a fee).

(d) **Federal Government**. Novo Nordisk acknowledges that the U.S. federal government retains a royalty-free, non-exclusive, non-transferable license to practice any government-funded invention claimed in any Whitehead Patent Rights as set forth in 35 U.S.C. §§ 201-211, and the regulations promulgated thereunder, as amended, or any successor statutes or regulations.

5.5.4 **Non-Use of Name**.

(a) Novo Nordisk and its Affiliates and Sublicensees shall not use the name of "Whitehead Institute" or any variation, adaptation, or abbreviation thereof, or of any of their trustees, officers, faculty, students, employees, or agents, or any trademark owned by Whitehead, or any terms of the Whitehead Licenses in any promotional material or other public announcement or disclosure, unless legally required, without the prior written consent of Whitehead, which consent Whitehead may withhold in its sole discretion. The foregoing notwithstanding, without the consent of Whitehead, Novo Nordisk may make factual statements during the term of this Agreement that Novo Nordisk has a license from Whitehead under one or more of the patents and/or patent applications comprising the Whitehead Patent Rights.

(b) Novo Nordisk and its Affiliates and Sublicensees may not use the name, logo, seal, trademark, service mark or domain names or other indicia of source, association or sponsorship of any Flagship Entity (as defined in the FPIV License), or any officer, director or other representative of any Flagship Entity (or any adaptation of any of the foregoing) without the prior written consent of such Flagship Entity, which consent will be granted or denied in such Flagship Entity's sole discretion.

5.5.5 **Whitehead and FPIV Reporting Obligations**. PlatformCo shall have the right to incorporate information received from Novo Nordisk under this Agreement solely to the extent required to fulfill its reporting obligations under the Whitehead Licenses and the FPIV

License. Novo Nordisk shall provide PlatformCo with written notice of the achievement of the events set forth on Schedule 5.5.5 promptly after such event becomes known to Novo Nordisk's Alliance Manager (but in no event later than [***] after such event).

5.6 **Transfer of PlatformCo Licensed Know-How Following Program Handoff Date**. Within [***] following the Program Handoff Date (or such earlier date as the Parties may agree in writing), PlatformCo shall, and if applicable, shall cause its Affiliates to, disclose and make available to Novo Nordisk at Novo Nordisk's sole cost and expense the PlatformCo Licensed Know-How in its and their possession that is [***] for the Exploitation of the IND-Enabling Candidate and Licensed Products pursuant to this Agreement; *provided* that, (i) if PlatformCo is conducting PlatformCo CMC Activities pursuant to Section 4.1.2(a) following the Program Handoff Date, then PlatformCo shall transfer all PlatformCo Licensed Know-How resulting from such PlatformCo CMC Activities within [***] following the earlier of (1) PlatformCo's completion of such PlatformCo CMC Activities; and (2) expiration of the Research Term in accordance with Section 1.273 and (ii) if a portion of such transfer remains incomplete at the end of the timeframe required under this Section 5.6, PlatformCo shall continue to exercise reasonable efforts to complete the transfer of the applicable PlatformCo Licensed Know-How to Novo Nordisk as soon as reasonably practicable. Such transfer shall be pursuant to the transition plan set forth in the R&D Plan and subject to the R&D Budget. In addition, PlatformCo shall provide written or verbal answers to Novo Nordisk's reasonable questions relating to the transferred PlatformCo Licensed Know-How and shall use reasonable efforts to make available PlatformCo's personnel who are knowledgeable about the Program for such purposes, *provided* that, Novo Nordisk shall reimburse PlatformCo at the then-current FTE Rate for such assistance. PlatformCo shall make such PlatformCo Licensed Know-How available in such form as maintained by PlatformCo. Novo Nordisk shall bear all Third Party expenses incurred by PlatformCo or its Affiliates in connection with the transfer of PlatformCo Licensed Know-How pursuant to this Section 5.6. [***].

6. EXCLUSIVITY.

6.1 **Exclusivity**.

6.1.1 **PM Entities**. Subject to this Article 6, during the Term (and for [***] if the Agreement is terminated prior to the Closing Date), except pursuant to this Agreement, none of the PM Entities shall, alone or with or for any Third Party (including through the grant of any license, option or other right to any Third Party, including any Flagship Affiliate), directly or indirectly, Exploit any Competing Product or any Field LNP Product anywhere in the Territory.

6.1.2 **Novo Nordisk**. Subject to this Article 6, until [***], except pursuant to this Agreement, neither Novo Nordisk nor any of its Affiliates shall, alone or with or for any Third Party (including through the grant of any license, option or other right to any Third Party), directly

or indirectly, Exploit any Competing Product comprising a Collaboration Epigenomic Controller anywhere in the Territory.

6.1.3 **Restricted Parties**. The PM Entities and Novo Nordisk are referred to herein as the "**Restricted Parties**."

6.2 **Exceptions to Exclusivity**. Notwithstanding anything to the contrary in Section 6.1:

6.2.1 **Acquired Competing Product**. If a Restricted Party or any of its Affiliates (such Party, the "**Distracted Restricted Party**") acquires a Third Party as the result of a merger, acquisition or combination with or of such Third Party other than a Change of Control (each, an "**Acquisition Transaction**") and, on the date of the completion of such Acquisition Transaction, such acquired Third Party is researching, Developing, Commercializing or otherwise Exploiting any compound or product that would, but for the provisions of this Section 6.2.1, constitute a breach of Section 6.1, as applicable (such product, an "**Acquired Competing Product**"), then the Distracted Restricted Party or such Affiliate shall, within [***] after the completion of such Acquisition Transaction, notify the Parties of such acquisition and the terms of this Section 6.2.1 shall apply.

(a) **PM Entities**. If any PM Entity is the Distracted Restricted Party, then such PM Entity may:

(i) request that such Acquired Competing Product be included in this Agreement on terms to be negotiated, which request Novo Nordisk may accept or reject in its sole discretion. If Novo Nordisk accepts such request to negotiate such terms, the Parties shall discuss the matter in good faith for a period of no less than [***] (or such longer period as may be agreed by the Parties). If Novo Nordisk rejects such request or, if Novo Nordisk and the applicable Distracted Restricted Party are unable to reach agreement on the terms on which such Acquired Competing Product would be included hereunder, then the Distracted Restricted Party shall elect to take the action specified in either clause (ii) or (iii) below; *provided* that the time periods specified in such clauses shall be tolled for so long as the Parties are engaged in discussion under this clause (i);

(ii) notify Novo Nordisk in writing that the Distracted Restricted Party or its Affiliate shall Divest its rights to such Acquired Competing Product, in which case, within [***] after the completion of the Acquisition Transaction, the Distracted Restricted Party or its Affiliate shall Divest such Acquired Competing Product; or

(iii) notify Novo Nordisk in writing that it is ceasing all such research, Development, Commercialization and other Exploitation activities with respect to the

Acquired Competing Product, in which case, within [***] thereafter the Distracted Restricted Party and its Affiliates shall cease all such activities.

During the discussion period under Section 6.2.1(a)(i), prior to the time of Divestiture pursuant to Section 6.2.1(a)(ii) or prior to the termination of activities pursuant to Section 6.2.1(a)(iii), as applicable, the Distracted Restricted Party and its Affiliates shall segregate all research, development or commercialization activities relating to the Competing Product from research, Development and Commercialization with respect to Epigenomic Controller-LNP Candidates and Licensed Products under this Agreement, including by requiring, and using Commercially Reasonable Efforts to ensure, that (x) no personnel involved in performing the research, development or commercialization of the Acquired Competing Product have access to non-public plans or information relating to the Exploitation of the Epigenomic Controller-LNP Candidate or Licensed Products hereunder ([***]) and (y) no personnel involved in performing the Exploitation of the Epigenomic Controller-LNP Candidate or Licensed Products have access to non-public plans or information relating to the Exploitation of such Competing Product ([***]). For the avoidance of doubt, if the agreement effecting a Divestiture is terminated, then the terms of this Section 6.2.1(a) shall again apply.

(b) **Novo Nordisk**. If Novo Nordisk is the Distracted Restricted Party, then the obligations of Section 6.1.2 shall not apply to such Acquired Competing Product comprising a Collaboration Epigenomic Controller, *provided*: (i) Novo Nordisk and its Affiliates establish and enforce internal processes, policies, procedures and systems to segregate information relating to any such program from any Confidential Information related to the Epigenomic Controller-LNP Candidate and Licensed Products under this Agreement during the Research Term, (ii) Novo Nordisk and its Affiliates do not use, directly or indirectly, (x) prior to the Closing Date, any PlatformCo Licensed IP, PM SpinCo Licensed IP or Confidential Information of PlatformCo or PM SpinCo or (y) following the Closing Date, any PlatformCo Licensed IP or Confidential Information of PlatformCo, in each case ((x) and (y)) to Exploit the Acquired Competing Product comprising a Collaboration Epigenomic Controller, and (iii) during the Research Term, no personnel involved in any Exploitation of the Acquired Competing Product comprising a Collaboration Epigenomic Controller have access to non-public plans or non-public information relating to the Exploitation of any Licensed Products (*provided* that management personnel may review and evaluate plans and information regarding the Exploitation of Licensed Products in connection with post-acquisition decision making).

6.2.2 **Change of Control**. If there is a Change of Control involving a Restricted Party (where such Restricted Party is the acquired entity), the obligations of Section 6.1 shall not apply to any compound or product that is Controlled by the relevant acquirer or its Affiliates that exist prior to the closing of such Change of Control; *provided* that (a) the acquired Restricted Party and the acquirer and its Affiliates existing immediately prior to the effective date of such Change of Control establish and enforce internal processes, policies, procedures and systems to segregate

information relating to any such program from any Confidential Information related to the Program, including any Epigenomic Controller-LNP Candidate and Licensed Products, (b) the acquirer and its Affiliates existing immediately prior to the effective date of such Change of Control do not use, directly or indirectly, any Patents, Know-How or Confidential Information of the acquired Restricted Party (including any Patents, Know-How or Confidential Information licensed or acquired from under this Agreement) in such program, and (c) no personnel who were employees or consultants of the acquired Restricted Party or its Affiliates (including, where the Restricted Party is a PM Entity, Flagship Labs, LLC) at any time prior to or after the Change of Control that have conducted or are conducting activities with respect to a Program Target shall conduct any activities under such program. Nothing in this Section 6.2.2 shall be deemed to provide consent by Novo Nordisk to a Change of Control of PM SpinCo. This Section 6.2.2 shall not apply to the acquisition of PM SpinCo by Novo Nordisk.

7. OPTION. PM SpinCo and PlatformCo each hereby acknowledge that Shareholder has granted Novo Nordisk the Option to purchase from Shareholder one hundred percent (100%) of the Subject Shares during the Option Exercise Period, on the terms and subject to the conditions set forth in the Option Agreement and the Share Purchase Agreement. Pursuant to the Option Agreement, Novo Nordisk shall exercise the Option, if at all, by giving written notice to PM SpinCo and Shareholder in accordance with the Option Agreement on or prior to the Option Termination Date. From and after the Closing Date, if any, any and all obligations of PM SpinCo to any PM Entity shall terminate, unless otherwise agreed by Novo Nordisk in writing.

8. FINANCIAL TERMS.

8.1 **Upfront Payment**. Subject to the terms and conditions of this Agreement, Novo Nordisk shall pay to PlatformCo a non-refundable, non-creditable (except as set forth in Section 8.7), and not subject to set-off payment in the amount of Five Million One Hundred Twenty-Five Thousand U.S. Dollars (US$ 5,125,000), which upfront payment shall be due and payable to PlatformCo within [***] following the Effective Date upon receipt of an invoice from PlatformCo (which shall be in the form set forth in Schedule 8.1).

8.2 **R&D Budget Reports; Reimbursement of Costs**.

8.2.1 On a Calendar Quarter-by-Calendar Quarter basis in advance, Novo Nordisk shall pay each RCA PM Party the amount set forth in the then current R&D Budget to be paid to such RCA PM Party for such Calendar Quarter. With respect to the first Calendar Quarter of the Research Term, unless subject to a bona fide dispute, Novo Nordisk shall pay such amount within [***]following receipt of invoice, and with respect to any subsequent Calendar Quarters, unless subject to a bona fide dispute, Novo Nordisk shall pay such amount within [***] after receipt thereof. With respect to each such subsequent Calendar Quarters, an RCA PM Party shall

deliver the applicable invoice no earlier than [***] prior to the commencement of such Calendar Quarter.

8.2.2 Within [***] after the end of each Calendar Quarter during the Research Term, each RCA PM Party shall deliver to the JRC a report tracking all R&D Costs actually incurred by such RCA PM Party during such Calendar Quarter against the then current R&D Plan and R&D Budget (each, an "**R&D Budget Report**"), including a breakdown of FTE Costs and Out-of-Pocket Costs, which reports shall also include any anticipated costs that may cause such RCA PM Party to exceed the then current R&D Budget for any future Calendar Quarter within such R&D Budget. The RCA PM Parties shall provide any documentation for such R&D Costs upon Novo Nordisk's reasonable request.

8.2.3 Within [***] following the end of each Calendar Quarter within the Research Term, or upon earlier termination of this Agreement, each RCA PM Party shall provide Novo Nordisk a report of the R&D Costs actually incurred by such RCA PM Party to conduct the R&D Activities allocated to such RCA PM Party during the applicable Calendar Quarter (the "**Research Term Incurred Costs**"), together with a breakdown of FTE Costs and Out-of-Pocket Costs and documentation therefor upon Novo Nordisk's request. To the extent the Research Term Incurred Costs as set forth in such report are less than the amounts actually paid by Novo Nordisk to such RCA PM Party to conduct the R&D Activities allocated to such RCA PM Party during the applicable Calendar Quarter (the "**Research Term Amounts Paid**") then, at Novo Nordisk's option, (a) such RCA PM Party shall pay Novo Nordisk, within [***] after receipt of an invoice therefor, an amount equal to the amount paid by Novo Nordisk for the applicable Calendar Quarter in excess of the Research Term Incurred Costs or (b) Novo Nordisk may offset against amounts owed to such RCA PM Party under this Agreement or the Option Agreement or Share Purchase Agreement, as applicable, an amount equal to the amount paid by Novo Nordisk for the applicable Calendar Quarter in excess of the Research Term Incurred Costs. To the extent the Research Term Incurred Costs for the applicable Calendar Quarter as set forth in such report exceed the Research Term Amounts Paid for the applicable Calendar Quarter and Novo Nordisk is responsible for such excess costs pursuant to Section 3.1.2, unless subject to a bona fide dispute, Novo Nordisk shall pay such RCA PM Party, within [***] after receipt of an invoice therefor, the amount incurred by such RCA PM Party in excess of the Research Term Amounts Paid for the applicable Calendar Quarter.

8.3 **Development Milestone Payment**. Except upon achievement of milestone event #1 set forth in this Section 8.3, in which case, PlatformCo shall notify Novo Nordisk in writing of the first achievement of such milestone by a Development Candidate [***] promptly after the occurrence thereof, Novo Nordisk shall notify PlatformCo in writing of the first achievement by or on behalf of Novo Nordisk, its Affiliates or Sublicensees of milestone events # 2-11 set forth in this Section 8.3 with respect to a Licensed Product [***] (each, a "**Development Milestone Event**") promptly after the occurrence thereof, and Novo Nordisk shall pay PlatformCo the

non-refundable, non-creditable (except as set forth in Section 8.7) milestone payment corresponding to such Development Milestone Event, as set forth in the table below (each, a "**Development Milestone Payment**") within [***] after Novo Nordisk's receipt of an invoice from PlatformCo following the achievement of Development Milestone Event #1 by the RCA PM Parties and Development Milestone Events #2-11 by Novo Nordisk, its Affiliates or any Sublicensees; *provided however*, that if [***]. For the avoidance of doubt, if the applicable Licensed Product is [***]. Development Milestone Payments are subject to set-off only as expressly set forth in this Agreement. Each of the Development Milestone Payments is payable only once under this Agreement upon the first such achievement of such Development Milestone Event by a Development Candidate or Licensed Product, as applicable, regardless of the number of times achieved by one or more Licensed Products.

Notwithstanding anything in the foregoing, if the IND-Enabling Tox Studies for the Development Candidate have not been initiated prior to the expiration of the Research Term, then Novo Nordisk shall notify PlatformCo in writing of the first achievement by or on behalf of Novo Nordisk, its Affiliates or Sublicensees of milestone event # 1 and promptly after the occurrence thereof, Novo Nordisk shall pay PlatformCo the applicable Development Milestone Payment as set forth above.

	Development Milestone Event	**Development Milestone Payment (in Dollars)**
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
4.	[***]	[***]
5.	[***]	[***]
6.	[***]	[***]
7.	[***]	[***]
8.	[***]	[***]
9.	[***]	[***]
10.	[***]	[***]
11.	[***]	[***]

Development Milestone Events #1-4 (only) are intended to be sequential. If a Licensed Product is not required to undergo any such Development Milestone Event, such skipped milestone(s) shall be deemed to have been achieved upon the achievement by such Licensed

Product of [***]. Payment for such skipped milestone that is owed in accordance with the provisions of the foregoing sentence shall be due concurrently with the payment for [***].

For clarity, subject to [***], Development Milestone Events #2-4 shall be deemed to have been achieved through [***] described by the Development Milestone Event, even if it is [***]. For example, Development Milestone Event #2 may be achieved upon [***] the 5th subject dosed in a Phase IA Clinical Trial, and Development Milestone Events #3 and #4 may [***].

8.4 **Sales Milestone Payments**. Novo Nordisk shall pay to PlatformCo the one-time Milestone Payments set forth below within [***] after Novo Nordisk's receipt of an invoice from PlatformCo following the first achievement by or on behalf of Novo Nordisk, its Affiliates or Sublicensees of the corresponding milestone event with respect to Net Sales of Licensed Products that are Covered by a Payment Claim in the applicable country in the Territory (each, a "**Sales Milestone Event**" and the corresponding payment, a "**Sales Milestone Payment**"); *provided however*, that [***]. For the avoidance of doubt, if [***]. Each Sales Milestone Payment is non-refundable, non-creditable (except as set forth in Section 8.7), and is payable only once under this Agreement upon the first such achievement of such Sales Milestone Event and none of the Sales Milestone Payments shall be payable more than once regardless of how many times such Sales Milestone Event is achieved by the Licensed Product(s) under this Agreement. Sales Milestone Payments are subject to set-off only as expressly set forth in this Agreement.

	Sales Milestone Event	**Sales Milestone Payment (in Dollars)**
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
4.	[***]	[***]
5.	[***]	[***]

Notwithstanding the foregoing, if more than one (1) Sales Milestone Events are first achieved in the same Calendar Year, then the highest unpaid Sales Milestone Payment earned shall be due and payable in such Calendar Year; *provided*, *however*, that any unpaid Sales Milestone Payment may be earned and become payable in subsequent Calendar Years. By way of example, if the #1 and #2 Sales Milestone Events set forth in the table above are first achieved in the same Calendar Year, then Novo Nordisk shall pay PlatformCo the US$[***] payment within [***] after Novo Nordisk's receipt of an invoice from PlatformCo therefor after the #1 Sales Milestone Event is achieved and a catch-up payment of US$[***] within [***] after Novo Nordisk's receipt of an invoice from PlatformCo therefor after the #2 Sales Milestone Event is achieved, with the result being, upon payment of such catch-up payment, that the #2 Sales Milestone Event shall be deemed

achieved and the #2 Sales Milestone Payment shall be deemed paid, and the #1 Sales Milestone Event shall be deemed not yet achieved and the #1 Sales Milestone Payment shall be deemed not yet paid. If the #1 Sales Milestone Event is then achieved in a subsequent Calendar Year and no other Sales Milestone Event is achieved in such subsequent Calendar Year, then Novo Nordisk shall pay PlatformCo the US$[***] payment within [***] after Novo Nordisk's receipt of an invoice from PlatformCo therefor after the #1 Sales Milestone Event is achieved. For the avoidance of doubt, no more than one (1) Sales Milestone Payment shall be earned under this Agreement, due and payable in any given Calendar Year.

8.5 **Royalties**.

8.5.1 **Royalty Rate**. Subject to the terms and conditions of this Agreement, on a Licensed Product-by-Licensed Product basis, during the applicable Royalty Term, Novo Nordisk shall pay to PlatformCo royalty payments at the royalty rates (the "**Royalty Rates**") specified in the following table with respect to the aggregate annual worldwide Net Sales of such Licensed Product in the Field in the Territory in a given Calendar Year:

	Aggregate Worldwide Net Sales of a Licensed Product in a Calendar Year	**Royalty Rate**
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
4.	[***]	[***]

8.5.2 **Royalty Term**. Royalty payments shall be due under Section 8.5 with respect to a given Licensed Product in a given country in the Territory during the period commencing upon the First Commercial Sale of such Licensed Product in such country and ending upon the latest of (a) the tenth (10th) anniversary of the First Commercial Sale of such Licensed Product in such country, (b) the expiration of the last-to-expire Payment Claim with respect to such Licensed Product in such country, or (c) expiration of Regulatory Exclusivity for such Licensed Product in such country (such period, the "**Royalty Term**" and such royalty payments, the "**Royalty Payments**"). After the expiration of the applicable Royalty Term with respect to a given Licensed Product in a given country in the Territory, no further Royalty Payments shall be due with respect to such Licensed Product in such country.

8.5.3 **Royalty Payments and Reports**. Within [***] after the end of each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of a Licensed Product is made anywhere in the Territory, Novo Nordisk shall provide to PlatformCo a report setting forth [***]; *provided, that* Novo Nordisk shall [***]. Promptly

following the delivery of the applicable quarterly report, PlatformCo shall invoice Novo Nordisk for the Royalty Payments and Sales Milestone Payments due to PlatformCo with respect to Net Sales by Novo Nordisk, its Affiliates and their respective Sublicensees for such Calendar Quarter. Novo Nordisk shall pay such amounts to PlatformCo within [***] following Novo Nordisk's receipt of such invoice.

8.5.4 **Milestone Payment and Royalty Payment Reductions**. The Milestone Payments payable under Section 8.3 and Section 8.4 and the Royalty Payments payable under Section 8.5.2 are subject to the following:

(a) **Third Party Payments**. Subject to the terms and conditions set forth in Section 10.10, on a Licensed Product-by-Licensed Product and country-by-country basis, if Novo Nordisk reasonably and in good faith determines in connection with a Licensed Product in a particular country in the Territory that it is [***] to obtain a license under a Third Party's Patents or Know-How to Develop, Manufacture or Commercialize such Licensed Product, then Novo Nordisk shall have the right (but not the obligation) to obtain such license (including by way of settlement of litigation). With respect to any such Patents or Know-How that are licensed by Novo Nordisk after the Effective Date the following terms shall apply:

(i) (A) with respect to Patents or Know-How that constitute NN Unknown Third Party Core IP, Novo Nordisk may deduct [***] of the amounts actually paid by Novo Nordisk to such Third Party that is attributable to such license for NN Unknown Third Party Core IP from [***] paid to PlatformCo under this Agreement for such Licensed Product in such country (including an equitably prorated portion of non-royalty payments under such license); and (B) with respect to any Other New IP, Novo Nordisk may deduct [***] of the amounts actually paid by Novo Nordisk to such Third Party that is attributable to such license for Other New IP from [***] otherwise due to PlatformCo under this Agreement for such Licensed Product in such country (including an equitably prorated portion of non-royalty payments under such license); *provided*, *however*, that in no event shall such deductions under this Section 8.5.4(a)(i) in aggregate reduce any [***] to less than the Payment Reduction Floor; and

(ii) with respect to Patents or Know-How that constitute NN Flagship Known Third Party Core IP, Novo Nordisk may deduct [***] of the amounts actually paid by Novo Nordisk to such Third Party that is attributable to such license for NN Flagship Known Third Party Core IP, from [***] paid to PlatformCo under this Agreement for such Licensed Product in such country (including an equitably prorated portion of non-royalty payments under such license), and such deduction under this Section 8.5.4(a)(ii) shall [***].

The [***] are subject to further reduction as set forth in Section 10.10.2. Offsets under this Section 8.5.4(a) are intended to be additive with the offsets regarding NN Unknown Third Party Core IP, Other New IP and NN Flagship Known Third Party Core IP, as applicable, in the Share Purchase Agreement and the Option Agreement, and nothing in this Agreement shall prevent Novo Nordisk

from taking offsets under this Section 8.5.4(a) as well as the foregoing offsets in the Share Purchase Agreement and the Option Agreement to the extent otherwise applicable.

(b) **Generic/Biosimilar Competition**. Subject to Section 8.5.4(d), on a Licensed Product-by-Licensed Product and country-by-country basis, if in any Calendar Quarter during the Royalty Term for a given Licensed Product in a country in the Territory, one or more Generic/Biosimilar Products are sold in such country [***], then the applicable Royalty Payments payable with respect to Net Sales of such Licensed Product in such country shall be reduced by [***]. If [***], Novo Nordisk may determine an alternative data source, which alternative shall be a reasonable and well-established data source widely used in the pharmaceutical industry.

(c) **Lack of Patent Protection**. Subject to Section 8.5.4(d) if at any time during the Royalty Term for a given Licensed Product in a particular country in the Territory, the [***] such Licensed Product in such country is not Covered by a Payment Claim, then the applicable [***] payable with respect to such Licensed Product in such country as specified in Section 8.5.2 shall be reduced by [***] of the [***] otherwise applicable for [***].

(d) **Cumulative Deductions**. Notwithstanding the foregoing, (i) in no event shall the deductions set forth in Section 8.5.4(b) and Section 8.5.4(c) in the aggregate reduce any [***] otherwise payable to PlatformCo as specified in Section 8.5.1 (as such [***] may be further reduced pursuant to Section 13.2.3(a)(ii)) by more than [***] and (ii) in no event shall [***] (as may be reduced pursuant to Section 8.5.4(b) and Section 8.5.4(c)) be further reduced due to operation of Sections 8.5.4(a)(i), 10.10.2(b)(ii)(B), 10.10.2(b)(iii), 10.10.2(c)(iii) or 10.10.2(c)(iv)(B) such that the cumulative reduction would result in any [***] of less than [***] of what would otherwise be payable to PlatformCo as specified in Sections 8.3, 8.4, or 8.5.1 (as such [***] may be further reduced pursuant to Section 13.2.3(a)(ii)) (each limit on payment reduction set forth in each of clauses (i) and (ii), the "**Payment Reduction Floor**"). If the foregoing limitations prevent Novo Nordisk from taking the full deduction to which it would otherwise be entitled, Novo Nordisk shall have the right to carry forward and deduct in a future period the portion of such deduction that it was prevented from taking by such limitations.

8.6 **Financial Audits**.

8.6.1 **Record Keeping**. Each Party and its Affiliates shall, and shall cause their respective Sublicensees and consultants to, keep complete, true and accurate books and records, in accordance with Accounting Standards, of the items underlying any payments due under this Agreement. Each Party and its Affiliates shall, and shall cause their respective Sublicensees and consultants to keep, such books and records during the Term and for at least [***] thereafter. Each Party (and with respect to the Whitehead Licenses, Whitehead or its appointed agent) (the "**Auditing Party**") shall have the right, not more than once annually (other than with respect to Whitehead and its appointed agent), at its own expense, to have an internationally-recognized independent, certified public accountant (the "**Auditor**"), selected by the Auditing Party and

acceptable to the Party being audited (the "**Audited Party**"), review any such records of the Audited Party and its Affiliates in the location(s) where such records are customarily maintained by the Audited Party and its Affiliates upon [***] prior written notice, during regular business hours and under obligations of confidentiality for the sole purpose of verifying the basis and accuracy of payments made under this Agreement, within the prior Calendar Year period after receipt of such report. The records for any Calendar Year may be audited no more than once with respect to records covering any specific period of time.

8.6.2 **Audit Report**. The report prepared by the Auditor, a copy of which shall be sent or otherwise provided to each Party by such Auditor at the same time before such report is considered final, shall contain the conclusions of such Auditor regarding the audit and shall specify that the amounts paid pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment, and the specific details regarding any discrepancies. No other information shall be provided to the Auditing Party without the prior consent of the Audited Party unless disclosure is required by Applicable Laws, regulation or judicial order, and if so determined by the Auditing Party, it shall, if permitted, give the Audited Party prior notice thereof to the extent possible for the Audited Party to seek a protective order against or otherwise prevent or limit such disclosure. If such report shows any underpayment, then the Audited Party shall remit to the Auditing Party, within [***] after receipt of such report, (a) the amount of such underpayment and (b) if such underpayment exceeds [***] of the total amount owed for the period then being audited, the actual fees charged by the Auditor in conducting such review. For the avoidance of doubt, any underpayment shall be considered a late payment, subject to Section 8.9. If such report shows any overpayment, then the Auditing Party shall, at the Auditing Party's election, credit the overpaid amount against future payments owed to the Auditing Party or reimburse the Audited Party the amount of such overpayment within [***] after receipt of such report. The Parties mutually agree that all information subject to review under this Section 8.6 is Confidential Information of the Audited Party and that the Auditing Party shall retain and cause the Auditor to retain all such information in confidence in accordance with confidentiality and non-use obligations no less stringent than those contained in Article 11. For the avoidance of doubt, the Audited Party is entitled to require the Auditor to execute a reasonable confidentiality agreement prior to commencing any such audit.

8.7 **Taxes**.

8.7.1 **Cooperation; Withholding**. The Parties agree to cooperate with one another and use reasonable efforts to minimize obligations for any and all taxes required by Applicable Law to be withheld or deducted from any royalties, milestone payments, or other payments made to each other under this Agreement, including by completing all procedural steps, and taking all reasonable measures, to ensure that any withholding tax is reduced or eliminated to the extent permitted under Applicable Law, including income tax treaty provisions and related procedures for claiming treaty relief. To the extent that Novo Nordisk is required to deduct and

withhold taxes on any payment to PlatformCo, Novo Nordisk shall deduct and withhold such taxes and any applicable interest and penalties from the applicable payment or from any other payment and pay the amounts of such taxes, interest, and penalties to the proper Governmental Authority in a timely manner and promptly submit to PlatformCo an official tax certificate or other evidence of such withholding sufficient to enable PlatformCo to claim such payment of taxes. Each Party shall provide the other Party with any tax forms that may be reasonably necessary in order for such Party to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral tax income treaty. PlatformCo shall use reasonable efforts to provide any such tax forms to Novo Nordisk at least [***] prior to the due date identified by Novo Nordisk for any payment for which PlatformCo desires that Novo Nordisk apply a reduced withholding rate. In the event that a Governmental Authority retroactively determines that a payment made by Novo Nordisk pursuant to this Agreement should have been subject to withholding or similar (or to additional withholding or similar) taxes, and Novo Nordisk remits such withholding or similar taxes to the Governmental Authority, Novo Nordisk will have the right (a) to offset such amount, including any interest and penalties that may be imposed thereon (except to the extent any such interest or penalties result from the negligence of Novo Nordisk), against future payment obligations of Novo Nordisk under this Agreement, the Option Agreement or the Share Purchase Agreement, or (b) to invoice PlatformCo for such amount (which shall be payable by PlatformCo within [***] of its receipt of such invoice).

8.7.2 **Tax Action**. Notwithstanding anything in this Agreement to the contrary, if an action (including but not limited to any assignment of its rights or obligations under this Agreement or any failure to comply with Applicable Laws or filing requirements) by a Party leads to the imposition of withholding tax liability or VAT on the other Party with respect to a payment made under this Agreement that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then (i) if the Party taking the action is the payor, the sum payable by such action Party shall be increased to the extent necessary to ensure that the other Party (in respect of which such deduction or withholding is required to be made) receives a sum equal to the sum which it would have received had no such action occurred, or (ii) if the Party taking the action is the recipient of the payment, the sum payable by the non-action Party shall be made to the other Party (in respect of which such deduction or withholding is required to be made) after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with Applicable Law.

8.7.3 **Taxes on Payments Received**. Notwithstanding anything to the contrary hereunder, each Party shall be solely responsible for the payment of any and all taxes levied on the payments such Party receives under this Agreement.

8.8 **Currency of Payments**. All amounts payable and calculations under this Agreement shall be in Dollars. As applicable, Net Sales and any royalty reductions shall be

translated into Dollars in the manner used by Novo Nordisk from time to time in the preparation of its audited financial statements for external reporting purposes. All payments under this Agreement shall be paid in Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing). If at any time legal restrictions prevent the prompt remittance of any Royalty Payments or other amounts with respect to any country where Licensed Products are sold, Novo Nordisk shall have the right, at its option, to make such payments by depositing, or causing to be deposited, the amount of such payments in local currency to PlatformCo's account in a bank or other depository designated by PlatformCo in such country.

8.9 **Late Payments**. Without limiting any other rights or remedies available to PlatformCo hereunder, any late payment by Novo Nordisk shall bear interest, to the extent permitted by Applicable Laws, at the rate of [***] as quoted by *The Wall Street Journal* (or if it no longer exists, a similarly authoritative source) calculated on a daily basis or the highest rate permitted by law (whichever is lower).

8.10 **Licensed Program Buyout**. Without limiting Section 15.5.2, following the Closing Date and subject to Section 15.5, upon Novo Nordisk's request, PlatformCo and Novo Nordisk shall negotiate in good faith and on commercially reasonable terms, for Novo Nordisk to buyout its future payment obligations under this Agreement (but neither PlatformCo nor Novo Nordisk shall be obligated to enter into any such buyout).

8.11 **Right to Offset**. Without limiting any other rights of Novo Nordisk under this Agreement, the Option Agreement, the Share Purchase Agreement or otherwise, Novo Nordisk shall have the right, but not the obligation, to set off, in whole or in part, against any obligation or payment it owes to PlatformCo under this Agreement, (a) any or all damages, liabilities, or indemnified amounts owed to Novo Nordisk by PlatformCo under this Agreement, or (b) any amounts claimed in good faith to be owed to Novo Nordisk by PlatformCo under this Agreement, *provided* that Novo Nordisk has provided written notice to PlatformCo setting forth the amount that Novo Nordisk claims to be owed pursuant to the terms of this Agreement, together with reasonable detail for the basis for such claim. If PlatformCo disputes that such amounts are owed to Novo Nordisk hereunder and initiates the dispute resolution process set forth in Article 14 with respect to such claim, then upon resolution pursuant to Article 14, Novo Nordisk shall pay to PlatformCo (i) the positive difference, if any, between the amounts withheld by Novo Nordisk pursuant to Section 8.11(b) and the amount of damages, liabilities, or indemnified amounts determined by the Executive Officers or arbitral tribunal, as applicable, to be owed to Novo Nordisk by PlatformCo *plus* (ii) interest from the date such amount was originally due and payable hereunder in accordance with Section 8.9. Without limiting the foregoing, any or all damages, liabilities, or indemnified amounts owed to Novo Nordisk by a PM Entity other than PlatformCo under this Agreement, or any such amounts claimed in good faith to be owed to Novo Nordisk by a PM Entity other than PlatformCo under this Agreement, may be set off by Novo Nordisk in

accordance with the provisions of Section 6.18 of the Option Agreement and Section 12.7 of the Share Purchase Agreement, as applicable.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMERS; LIMITATION OF LIABILITY.

9.1 **Mutual Representations and Warranties**. As a material inducement to the other Parties entering into this Agreement, each Party represents and warrants to the other Parties as of the Effective Date that:

9.1.1 such Party is duly organized, validly existing and in good standing (or to the extent such concept is not applicable in the relevant jurisdiction, is up to date in filing its corporate returns) under the Applicable Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and (in the case of PM SpinCo and Novo Nordisk) the Option Agreement and to carry out the provisions hereof and thereof;

9.1.2 the execution of this Agreement and the performance by such Party of its obligations hereunder and thereunder have been duly authorized;

9.1.3 this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, binding obligation enforceable against it in accordance with the terms hereof;

9.1.4 the execution, delivery and performance of this Agreement by such Party do not conflict with or constitute, with or without the passage of time or the giving of notice or both, a breach or default under any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Laws of any court, governmental body or administrative or other agency having jurisdiction over such Party; and

9.1.5 no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under any Applicable Laws in effect as of the Effective Date, is necessary in connection with the execution and delivery of this Agreement, or for the performance by such Party of its obligations under this Agreement, except as may be required under the Share Purchase Agreement or for any such consent or approval obtained prior to the Effective Date.

9.2 **Representations and Warranties of PlatformCo**. As a material inducement to Novo Nordisk and PM SpinCo entering into this Agreement, PlatformCo hereby represents and warrants to Novo Nordisk and PM SpinCo, as of the Effective Date, that:

9.2.1 a complete and accurate list of all PlatformCo Licensed Patents existing as of the Effective Date is set forth in Schedule 1.217 (the "**PlatformCo Existing Patents**"),

indicating the owner, licensor or co-owner(s) as applicable. To the Knowledge of PlatformCo, all PlatformCo Existing Patents are valid, subsisting and enforceable;

9.2.2 to the Knowledge of PlatformCo, the conduct of the R&D Activities contemplated under the R&D Plan as of the Effective Date will not infringe any Patents (for the purpose of such representation and warranty, disregarding any effect of the safe harbor of 35 U.S.C. § 271(e)(1)) or misappropriate any materials, Know-How or other Intellectual Property of any Third Party;

9.2.3 (a) PlatformCo has received no written claims, and (b) there is no (i) pending litigation to which PlatformCo is a party, or (ii) to the Knowledge of PlatformCo, (A) threatened claim or litigation against PlatformCo or (B) threatened or pending claim or litigation against any Third Party, in each case of (a) and (b) challenging the validity, enforceability or ownership or in-license, as applicable, by PlatformCo of any PlatformCo IP. There are no legal or governmental proceedings pending with respect to any PlatformCo IP, other than review of pending Patent applications. To the Knowledge of PlatformCo, there is no unauthorized use, infringement, or misappropriation of any PlatformCo IP by any Third Party;

9.2.4 PlatformCo has the right to grant all rights and licenses it purports to grant to Novo Nordisk with respect to the PlatformCo IP;

9.2.5 PlatformCo has not granted any right or license to any Third Party relating to any of the PlatformCo IP that conflicts or interferes with any of the rights or licenses granted to Novo Nordisk hereunder;

9.2.6 neither PlatformCo nor any of its Affiliates has granted any liens or security interests on the PlatformCo IP and the PlatformCo IP is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind;

9.2.7 to the Knowledge of PlatformCo, all information provided by PlatformCo or any of its Affiliates to Novo Nordisk with respect to the PlatformCo IP is true and correct in all material respects;

9.2.8 all PlatformCo Existing Patents Prosecuted and Maintained by PlatformCo have been, for the period of time PlatformCo has controlled the Prosecution and Maintenance of such Patents and, to the Knowledge of PlatformCo, at all other times, filed and diligently Prosecuted and Maintained in accordance with all Applicable Laws in the countries in which Patents have been filed and have been maintained with all applicable fees due prior to the Effective Date with respect thereto having been paid, including all applicable requirements of Patent offices and all other applicable Governmental Authorities in countries in which Patents have been filed to maintain the PlatformCo Existing Patents in full force and effect, including payment of all required fees when due to such offices or agencies;

9.2.9 PlatformCo has obtained from all PlatformCo employees and consultants who shall or may be involved in the creation or development of any portion of the PlatformCo IP or who shall or may be involved in Development activities under this Agreement, written assignments to PlatformCo of any Intellectual Property created or developed by such employees or consultants and has complied with all applicable procedures relating to such assignments mandated by Applicable Laws;

9.2.10 PlatformCo has not employed, and to the Knowledge of PlatformCo, has not used, a contractor or consultant that has employed or is employing any individual or entity (a) debarred by the FDA pursuant to Section 306 of the FD&C Act (21 U.S.C. § 335a) (or subject to a similar sanction of the EMA or other applicable Regulatory Authority), (b) who is the subject of an FDA debarment investigation or proceeding (or similar proceeding of the EMA or other applicable Regulatory Authority), or (c) who has been charged or convicted under Applicable Laws of the United States for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992, in each case, in the conduct of its activities prior to the Effective Date;

9.2.11 Schedule 1.312 sets forth a complete and accurate list of all Upstream Licenses. PlatformCo has Delivered to Novo Nordisk true, complete and accurate copies of all Upstream Licenses in effect as of the Effective Date;

9.2.12 PlatformCo has not received any written notice alleging any breach of any Upstream License; and

9.2.13 PlatformCo does not Control any Program Tissue LNP or other Delivery or Formulation Technology capable of delivering a therapeutic composition or product to the Program Tissue.

9.3 **Representations and Warranties of PM SpinCo**. As a material inducement to Novo Nordisk and PlatformCo entering into this Agreement, PM SpinCo hereby represents and warrants to Novo Nordisk and PlatformCo, as of the Effective Date, that, except as set forth in a disclosure letter provided by PM SpinCo to Novo Nordisk and PlatformCo as of the Effective Date:

9.3.1 a complete and accurate list of all PM SpinCo Licensed Patents existing as of the Effective Date is set forth on Schedule 1.229 (the "**PM SpinCo Existing Patents**"), indicating the owner, or co-owner(s) as applicable. None of the PM SpinCo Existing Patents are licensed to PM SpinCo by any Third Party, including any Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries. To the Knowledge of PM SpinCo, all PM SpinCo Existing Patents are valid, subsisting and enforceable;

9.3.2 to the Knowledge of PM SpinCo, the conduct of the R&D Activities contemplated under the R&D Plan as of the Effective Date will not infringe any Patents (for the purpose of such representation and warranty, disregarding any effect of the safe harbor of 35 U.S.C. § 271(e)(1)) or misappropriate any materials, Know-How or other Intellectual Property of any Third Party;

9.3.3 PM SpinCo has the right to grant all rights and licenses it purports to grant to Novo Nordisk with respect to the PM SpinCo IP;

9.3.4 PM SpinCo has not granted any right or license to any Third Party relating to any of the PM SpinCo IP that conflicts or interferes with any of the rights or licenses granted to Novo Nordisk hereunder;

9.3.5 neither PM SpinCo nor any of its Affiliates has granted any liens or security interests on the PM SpinCo IP and the PM SpinCo IP is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind;

9.3.6 to the Knowledge of PM SpinCo, all information provided by PM SpinCo or any of its Affiliates to Novo Nordisk with respect to the PM SpinCo IP is true and correct in all material respects;

9.3.7 (a) PM SpinCo has received no written claims, and (b) there is no (i) pending litigation to which PM SpinCo is a party, or (ii) to the Knowledge of PM SpinCo, (A) threatened claim or litigation against PM SpinCo or (B) threatened or pending claim or litigation against any Third Party, in each case of (a) and (b) challenging the validity, enforceability or ownership or in-license, as applicable, by PM SpinCo of any PM SpinCo IP. There are no legal or governmental proceedings pending with respect to any PM SpinCo IP, other than review of pending Patent applications. To the Knowledge of PM SpinCo, there is no unauthorized use, infringement, or misappropriation of any PM SpinCo IP by any Third Party;

9.3.8 all PM SpinCo Existing Patents Prosecuted and Maintained by PM SpinCo have been, for the period of time PM SpinCo has controlled the Prosecution and Maintenance of such Patents and, to the Knowledge of PM SpinCo, at all other times, filed and diligently Prosecuted and Maintained in accordance with all Applicable Laws in the countries in which Patents have been filed and have been maintained with all applicable fees due prior to the Effective Date with respect thereto having been paid, including all applicable requirements of Patent offices and all other applicable Governmental Authorities in countries in which Patents have been filed to maintain the PM SpinCo Existing Patents in full force and effect, including payment of all required fees when due to such offices or agencies;

9.3.9 PM SpinCo has obtained from all PM SpinCo employees and consultants who shall or may be involved in the creation or development of any portion of the PM SpinCo IP

or who shall or may be involved in Development activities under this Agreement, written assignments to PM SpinCo of any Intellectual Property created or developed by such employees or consultants and has complied with all applicable procedures relating to such assignments mandated by Applicable Laws; and

9.3.10 PM SpinCo has not employed, and to the Knowledge of PM SpinCo, has not used, a contractor or consultant that has employed or is employing any individual or entity (a) that was or is currently debarred by the FDA pursuant to Section 306 of the FD&C Act (21 U.S.C. § 335a) (or subject to a similar sanction of the EMA or other applicable Regulatory Authority), (b) who is the subject of an FDA debarment investigation or proceeding (or similar proceeding of the EMA or other applicable Regulatory Authority), or (c) who has been charged or convicted under Applicable Laws of the United States for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992, in each case, in the conduct of its activities prior to the Effective Date.

9.4 **PlatformCo Covenants**. PlatformCo hereby covenants to PM SpinCo and Novo Nordisk that, during the Term:

9.4.1 PlatformCo shall carry out its Program activities pursuant to this Agreement in material compliance with all Applicable Laws.

9.4.2 PlatformCo shall not employ (or use any contractor, consultant or other service provider that to the Knowledge of PlatformCo employs) any individual or entity that it knows (a) is debarred by the FDA pursuant to Section 306 of the FD&C Act (21 U.S.C. § 335a) (or subject to a similar sanction of the EMA or other applicable Regulatory Authority), (b) is the subject of an FDA debarment investigation or proceeding (or similar proceeding of the EMA or other applicable Regulatory Authority), or (c) who has been charged or convicted under Applicable Laws for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992. If, during the Term, PlatformCo has reason to believe that it or any employee, officer, contractor, consultant or other service provider: (i) is or will be debarred or charged or convicted under Applicable Laws for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992; (ii) is or will be under indictment for a crime for which an individual or entity could be debarred under Section 306 of the FD&C Act, then PlatformCo shall promptly notify PlatformCo of the same in writing.

9.4.3 PlatformCo (a) shall not terminate the Upstream Licenses, (b) shall promptly notify Novo Nordisk if it receives or gives notice of any breach or default under any such agreement, (c) shall not amend or modify any of the Upstream Licenses (including any side letter, consent or waiver agreement entered into with the applicable Upstream Licensor in connection with this Agreement) in any manner materially adverse to the rights of Novo Nordisk under this Agreement absent the prior written approval of Novo Nordisk (such approval not to be

unreasonably withheld, conditioned or delayed), and (d) shall notify Novo Nordisk if, during the Term of this Agreement, any Upstream License is terminated or expires.

9.4.4 PlatformCo shall not sell, license or otherwise transfer to any Third Party or PlatformCo Affiliate (other than a Subsidiary or PM SpinCo) any PlatformCo Licensed IP or PlatformCo's interest in the PM and NN Joint Developed IP or RCA PM Parties Joint Developed IP if such sale, license or transfer would conflict with any of the rights or licenses granted to Novo Nordisk hereunder.

9.5 **PM SpinCo Covenants**. PM SpinCo hereby covenants to PlatformCo and Novo Nordisk that, during the Term:

9.5.1 PM SpinCo shall carry out its Program activities pursuant to this Agreement in material compliance with all Applicable Laws.

9.5.2 PM SpinCo shall not employ (or use any contractor, consultant or other service provider that to the Knowledge of PM SpinCo employs) any individual or entity that it knows (a) is debarred by the FDA pursuant to Section 306 of the FD&C Act (21 U.S.C. § 335a) (or subject to a similar sanction of the EMA or other applicable Regulatory Authority), (b) is the subject of an FDA debarment investigation or proceeding (or similar proceeding of the EMA or other applicable Regulatory Authority), or (c) who has been charged or convicted under Applicable Laws for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992. If, during the Term, PM SpinCo has reason to believe that it or any employee, officer, contractor, consultant or other service provider: (i) is or will be debarred or charged or convicted under Applicable Laws for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992; (ii) is or will be under indictment for a crime for which an individual or entity could be debarred under Section 306 of the FD&C Act, then PM SpinCo shall promptly notify Novo Nordisk of the same in writing.

9.5.3 PM SpinCo shall not sell, license or otherwise transfer to any Third Party, (including PlatformCo, except to the extent expressly authorized under this Agreement) or PM SpinCo Affiliate (other than a Subsidiary) any PM SpinCo Licensed IP or PM SpinCo's interest in the Joint PM and NN Joint Developed IP or RCA PM Parties Joint Developed IP if such sale, license or transfer would conflict with any of the rights or licenses granted to Novo Nordisk hereunder.

9.6 **Representations and Warranties of Novo Nordisk**.

9.6.1 Novo Nordisk hereby represents and warrants to PlatformCo and PM SpinCo, as of the Effective Date, that Novo Nordisk is treated as a corporation for U.S. federal income tax purposes.

9.7 **Covenants of Novo Nordisk**. Novo Nordisk hereby covenants to PlatformCo and PM SpinCo that, during the Term:

9.7.1 Novo Nordisk shall carry out its activities pursuant to this Agreement in material compliance with all Applicable Laws.

9.7.2 Novo Nordisk has not been and is not currently, and shall not employ (or use any contractor, consultant or other service provider that to the knowledge of Novo Nordisk employs) any individual or entity that it knows is (a) debarred by the FDA pursuant to Section 306 of the FD&C Act (21 U.S.C. § 335a) (or subject to a similar sanction of the EMA or other applicable Regulatory Authority), (b) the subject of an FDA debarment investigation or proceeding (or similar proceeding of the EMA or other applicable Regulatory Authority), or (c) charged or convicted under Applicable Laws for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992. If during the Term Novo Nordisk has reason to believe that it or any employee, officer, contractor, consultant or other service provider: (i) is or will be debarred or charged or convicted under Applicable Laws for conduct relating to Development or Regulatory Approval of, or other activities for, any product covered by the Generic Drug Enforcement Act of 1992; (ii) is or will be under indictment for a crime for which an individual or entity could be debarred under Section 306 of the FD&C Act, then Novo Nordisk shall promptly notify PlatformCo of the same in writing.

9.8 **Disclaimers**. EXCEPT AS EXPRESSLY SET FORTH IN SECTIONS 9.1, 9.2, 9.3, AND 9.6, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND UNDER THIS AGREEMENT, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OR VALIDITY OF ANY PATENTS ISSUED OR PENDING, OR WITH RESPECT TO THE OUTCOME OR RESULTS OF ANY ACTIVITIES TO BE PERFORMED PURSUANT TO THE PROGRAM OR ANY OTHER ACTIVITIES UNDER THIS AGREEMENT.

9.9 **Other Agreements; Cooperation**.

9.9.1 **Notice of Challenges to Transactions**. Each Party shall immediately notify the other Parties of any action, suit or proceeding instituted or threatened against such Party to restrain, prohibit or otherwise challenge the legality of any transaction contemplated by this Agreement, the Option Agreement or the Share Purchase Agreement.

9.9.2 **Cooperation**. The Parties agree to provide reasonable cooperation with each other and to execute and deliver such further documents, certificates, agreements and instruments and to take such other actions as may be reasonably requested by the other Parties to evidence or reflect the transactions contemplated by this Agreement and to carry out the intent and

purposes of this Agreement, and, in the case of PM SpinCo and Novo Nordisk, the Option Agreement and only if the Option is exercised, the Share Purchase Agreement.

10. INTELLECTUAL PROPERTY.

10.1 **Inventions Generally**. Inventorship of inventions conceived or reduced to practice in the course of activities performed under this Agreement shall be determined by application of U.S. Patent laws pertaining to inventorship.

10.2 **Ownership of Background IP**. Each Party shall retain ownership of all right, title, and interest in and to any Patents and Know-How that it Controls prior to the Effective Date of this Agreement or that such Party develops or acquires outside the scope of this Agreement (collectively, "**Background IP**").

10.3 **Ownership of Developed IP**.

10.3.1 **RCA PM Parties Joint Developed IP**. Except as set forth in Section 10.3.5, as among the Parties, any Know-How conceived, discovered, developed, or otherwise made (i) solely by or on behalf of PM SpinCo (or its Affiliates, independent contractors or sublicensees) in the conduct of activities [***], (ii) solely by or on behalf of PlatformCo (or its Affiliates, independent contractors or sublicensees) in the conduct of activities [***], or (iii) jointly by or on behalf of PM SpinCo and PlatformCo (or their respective Affiliates, independent contractors or sublicensees) in the conduct of activities [***] (collectively, the "**RCA PM Parties Joint Developed Know-How**") and any Patents that Cover such Know-How (the "**RCA PM Parties Joint Developed Patents**" and together with the RCA PM Parties Joint Developed Know-How, the "**RCA PM Parties Joint Developed IP**"), shall be owned jointly by the RCA PM Parties on an equal and undivided basis, including all rights, title and interest thereto, subject to any rights or licenses expressly granted by an RCA PM Party to the other Parties under this Agreement. Each RCA PM Party hereby agrees to assign, and to cause its Affiliates, independent contractors or sublicensees to assign, and hereby assigns to the other RCA PM Party, who accepts such assignment, such portion of its right, title, and interest in, to and under the RCA PM Parties Joint Developed IP as required for the RCA PM Parties to jointly own the RCA PM Parties Joint Developed IP. Except as expressly provided in this Agreement, neither RCA PM Party shall have any obligation to account to the other RCA PM Party for profits with respect to, or to obtain any consent of the other RCA PM Party to license or exploit, such RCA PM Parties Joint Developed IP by reason of joint ownership thereof, and each RCA PM Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting. Each RCA PM Party shall take all actions and provide the other RCA PM Party with all reasonably requested assistance to effect such assignment and shall execute any and all documents necessary to perfect such assignment. For those countries where a specific license is required for a joint owner of the RCA PM Parties Joint Developed IP to practice such RCA PM Parties Joint Developed IP in such countries, each RCA PM Party hereby grants to the other RCA PM Party a perpetual, irrevocable,

non-exclusive, worldwide, royalty-free, fully paid-up license, with the right to grant sublicenses through multiple tiers, under such RCA PM Party's right, title and interest in and to all RCA PM Parties Joint Developed IP to use such RCA PM Parties Joint Developed IP for any purpose. Any Know-How conceived, discovered, developed, or otherwise made solely by or on behalf of PM SpinCo (or its Affiliates, independent contractors or sublicensees) from and after the Closing Date, and any Patents that Cover such Know-How, shall be owned by PM SpinCo and shall not be RCA PM Parties Joint Developed IP.

10.3.2 **Novo Nordisk Developed IP**. Except as set forth in Section 10.3.5, as among the Parties, Novo Nordisk shall be the sole owner of any Know-How conceived, discovered, developed, or otherwise made solely by or on behalf of Novo Nordisk (or its Affiliates (including, after the Closing Date, PM SpinCo), independent contractors or sublicensees (including Sublicensees)) in the conduct of activities [***] (the "**Novo Nordisk Developed Know-How**") and any Patents that Cover such Know-How (the "**Novo Nordisk Developed Patents**" and together with the Novo Nordisk Developed Know-How, the "**Novo Nordisk Developed IP**"), and shall retain all of its rights, title and interest thereto, subject to any rights or licenses expressly granted by Novo Nordisk to PM SpinCo or PlatformCo under this Agreement.

10.3.3 **PM and NN Joint Developed IP**.

(a) **Prior to the Program Handoff Date**. Except as set forth in Section 10.3.5, as among the Parties, any Know-How conceived, discovered, developed, or otherwise made jointly by or on behalf of an RCA PM Party and Novo Nordisk (or their respective Affiliates, independent contractors or sublicensees (including Sublicensees)) in the conduct of activities [***] (the "**PM and NN Joint Developed Know-How**") and any Patents that Cover such Know-How (the "**PM and NN Joint Developed Patents**," and together with the PM and NN Joint Developed Know-How, the "**PM and NN Joint Developed IP**"), shall be owned jointly by the RCA PM Parties and Novo Nordisk on an equal and undivided basis, including all rights, title and interest thereto, subject to any rights or licenses expressly granted by a Party to the other Parties under this Agreement. Each Party hereby agrees to assign, and to cause its Affiliates, independent contractors or sublicensees to assign, and hereby assigns to the other Parties, who accept such assignment, such portion of its right, title, and interest in, to and under the PM and NN Joint Developed IP as required for the Parties to jointly own the PM and NN Joint Developed IP. Except as expressly provided in this Agreement, neither the RCA PM Parties nor Novo Nordisk shall have any obligation to account to the other Parties for profits with respect to, or to obtain any consent of the other Parties to license or exploit, such PM and NN Joint Developed IP by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting. Each Party shall take all actions and provide the other Parties with all reasonably requested assistance to effect such assignment and shall execute any and all documents necessary to perfect such assignment. For those countries where a specific license is required for a joint owner of PM and NN Joint Developed IP to practice such

PM and NN Joint Developed IP in such countries, each Party hereby grants to the other Party a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, with the right to grant sublicenses through multiple tiers, under such Party's right, title and interest in and to all PM and NN Joint Developed IP to use such PM and NN Joint Developed IP subject to the terms and conditions of this Agreement.

(b) **Following the Program Handoff Date**.

(i) Any Know-How conceived, discovered, developed, or otherwise made jointly by or on behalf of PM SpinCo and Novo Nordisk (or their Affiliates, independent contractors or sublicensees, but excluding for clarity PlatformCo or its Affiliates, independent contractors or sublicensees) in the conduct of activities [***], and any Patents that Cover such Know-How, shall be owned jointly by PM SpinCo and Novo Nordisk and shall not be PM and NN Joint Developed IP.

(ii) Any Know-How conceived, discovered, developed, or otherwise made jointly by or on behalf of PM SpinCo or Novo Nordisk (or their Affiliates, independent contractors or sublicensees (including Sublicensees)), on the one hand and PlatformCo (or its Affiliates, independent contractors or sublicensees), on the other hand, in the conduct of activities [***], and any Patents that Cover such Know-How, shall be PM and NN Joint Developed IP.

10.3.4 **Disclosure**. Each Party shall promptly disclose to the other Parties in writing, and shall cause its Affiliates and Third Parties acting on their behalf to so disclose, the discovery, development, invention or creation of any Know-How developed, invented or created by such Party or its Affiliates or Third Parties acting on their behalf in the conduct of activities [***].

10.3.5 **Exceptions**.

(a) **Collaboration Epigenomic IP**.

(i) As among the Parties, PlatformCo shall solely own all Collaboration Epigenomic IP, except as set forth in Section 10.3.5(a)(ii) below.

(ii) Novo Nordisk (and PM SpinCo after the Program Handoff Date) shall retain . [***].

(iii) Novo Nordisk and PM SpinCo shall each promptly disclose to PlatformCo in writing, and shall cause its Affiliates to so disclose, the discovery, development, invention or creation of any Collaboration Epigenomic IP developed, invented or created by such Party or its Affiliates or Third Parties acting on their behalf in the conduct of activities [***]. PM

SpinCo and Novo Nordisk hereby agree to assign, and to cause their Affiliates to assign, and hereby assign, to PlatformCo all of their, and their Affiliates', right, title and interest in and to the Collaboration Epigenomic IP (other than the Collaboration Epigenomic Know-How as set forth in Section 10.3.5(a)(ii)). PM SpinCo and Novo Nordisk shall take all actions and provide PlatformCo with all reasonably requested assistance to effect such assignment and shall execute any and all documents necessary to perfect such assignment. The Parties shall discuss in good faith whether to submit Patent applications with respect to Collaboration Epigenomic Know-How retained by Novo Nordisk pursuant to Section 10.3.5(a)(ii), but PlatformCo shall have the final decision-making authority with respect to any determination of whether to submit, and will have the sole right, but not the obligation, to Prosecute and Maintain all Patents with respect to Collaboration Epigenomic Know-How.

(b) **LNP Joint IP**. As among the Parties, LNP Joint IP shall be owned jointly by the RCA PM Parties and Novo Nordisk on an equal and undivided basis, including all rights, title and interest thereto, subject to any rights or licenses expressly granted by a Party to the other Parties under this Agreement. Each Party hereby agrees to assign, and to cause its Affiliates, independent contractors or sublicensees to assign, and hereby assigns to the other Parties, who accept such assignment, such portion of its right, title, and interest in, to and under the LNP Joint IP as required for the Parties to jointly own the LNP Joint IP. Except as expressly provided in this Agreement, neither the RCA PM Parties nor Novo Nordisk shall have any obligation to account to the other Parties for profits with respect to, or to obtain any consent of the other Parties to license or exploit, such LNP Joint IP by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting. Each Party shall take all actions and provide the other Parties with all reasonably requested assistance to effect such assignment and shall execute any and all documents necessary to perfect such assignment. For those countries where a specific license is required for a joint owner LNP Joint IP to practice such LNP Joint IP in such countries, each Party hereby grants to the other Party a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, with the right to grant sublicenses through multiple tiers, under such Party's right, title and interest in and to all LNP Joint IP to use such LNP Joint IP subject to the terms and conditions of this Agreement.

(c) **Novo Nordisk Background Improvements.** As among the Parties, Novo Nordisk shall solely own any modification, enhancement or change to Novo Nordisk Collaboration Background IP that is conceived, discovered, developed, or otherwise made solely by or on behalf of any Party (or its Affiliates, independent contractors or sublicensees) in the conduct of activities [***] or jointly by or on behalf of any of the Parties (or their respective Affiliates, independent contractors or sublicensees) in the conduct of activities [***] (the "**NN Background Improvements**"). The RCA PM Parties hereby agree to assign, and to cause their Affiliates to assign, and hereby assign, to Novo Nordisk all of their, and their Affiliates', right, title and interest in and to the NN Background Improvements. The RCA PM Parties shall each promptly disclose to Novo Nordisk in writing, and shall cause its Affiliates to so disclose, the

discovery, development, invention or creation of any NN Background Improvements developed, invented or created by such Party or its Affiliates or Third Parties acting on their behalf in the conduct of activities [***]. The RCA PM Parties shall take all actions and provide Novo Nordisk with all reasonably requested assistance to effect such assignment and shall execute any and all documents necessary to perfect such assignment.

(d) **Improvements to Disclosed PlatformCo Background Patents**. In the event that any modification, enhancement or change to any inventions claimed in any PlatformCo Licensed Patent listed on Schedule 1.217 or any other Patent Controlled by PlatformCo prior to the Effective Date and listed on Schedule 10.3.5(d) is conceived, discovered, developed, or otherwise made solely by or on behalf of any Party (or its Affiliates, independent contractors or sublicensees) in the conduct of activities [***] or jointly by or on behalf of any of the Parties (or their respective Affiliates, independent contractors or sublicensees) in the conduct of activities [***] (the "**PlatformCo Background Improvements**"), [***]. Novo Nordisk and PM SpinCo shall each promptly disclose to PlatformCo in writing, and shall cause its Affiliates to so disclose, the discovery, development, invention or creation of any PlatformCo Background Improvements developed, invented or created by such Party or its Affiliates or Third Parties acting on their behalf in the conduct of activities [***]. Novo Nordisk and PM SpinCo shall take all actions and provide PlatformCo with all reasonably requested assistance to effect such assignment and shall execute any and all documents necessary to perfect the assignment contemplated by this Section 10.3.5(d). The Parties shall discuss in good faith whether to submit Patent applications with respect to PlatformCo Background Improvements consisting of Know-How retained by Novo Nordisk pursuant to this Section 10.3.5(d), but PlatformCo shall have the final decision-making authority with respect to any determination of whether to submit, and will have the sole right, but not the obligation, to Prosecute and Maintain all Patents with respect to PlatformCo Background Improvements.

10.3.6 **Assignment Obligation**. Each Party shall cause all employees of such Party who perform activities for such Party under this Agreement to be under an obligation to assign their rights in any Patents and Know-How, whether or not patentable, resulting therefrom to such Party to effectuate the terms and conditions set forth in this Section 10.3. With respect to any activities of a Party under this Agreement that are subcontracted to a Person that is not an employee (including an Affiliate, independent contractor, sublicensee or Flagship Labs, LLC), the Party retaining such subcontractor shall use reasonable efforts to include in the applicable subcontract an assignment to such subcontracting Party of all rights in Patents and Know-How made by such subcontractor resulting from such activities, and in any event shall include in the applicable subcontract a license to such subcontracting Party that is sublicensable to the other Party under this Agreement, of any Patents that specifically claim a Licensed Product, Know-How to the extent applicable to a Licensed Product, any Collaboration Epigenomic IP and, in each case, made by such contractor or subcontractor resulting from such activities.

10.4 **Prosecution and Maintenance of Patents**.

10.4.1 **General Licensed Patents; Licensed Epigenomic Controller Patents**. As among the Parties, other than with respect to the Joint Patents, PM SpinCo (or after the Program Handoff Date, Novo Nordisk) shall have the sole right, but not the obligation, to Prosecute and Maintain all General PM SpinCo Licensed Patents in the Territory at PM SpinCo's (or after the Program Handoff Date, Novo Nordisk's) expense with counsel of its choice. As among the Parties, (a) other than with respect to the Joint Patents, PlatformCo shall have the sole right, but not the obligation, to Prosecute and Maintain all General PlatformCo Licensed Patents in the Territory and (b) PlatformCo shall have the sole right, but not the obligation, to Prosecute and Maintain all Licensed Epigenomic Controller Patents in the Territory, in each case ((a) and (b)) at PlatformCo's expense with counsel of its choice.

10.4.2 **Joint Patents**.

(a) **RCA PM Parties Joint Developed Patents**. As among the Parties, other than with respect to the Licensed Product-Specific Patents (which are addressed in Section 10.4.4), the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall have the sole right, but not the obligation, to Prosecute and Maintain all RCA PM Parties Joint Developed Patents in the Territory at the RCA PM Parties' (or after the Program Handoff Date, PlatformCo's) expense with counsel of their choice.

(b) **PM and NN Joint Developed Patents and LNP Joint Patents**.

(i) **Prior to the Program Handoff Date**. Prior to the Program Handoff Date, as among the Parties, other than with respect to the Licensed Product-Specific Patents (which are addressed in Section 10.4.4), Novo Nordisk on the one hand and the RCA PM Parties on the other hand shall jointly Prosecute and Maintain all PM and NN Joint Developed Patents and LNP Joint Patents in the Territory. Decisions regarding such Prosecution and Maintenance shall be made by the Parties through the JPC. Expenses for such Prosecution and Maintenance shall be shared equally by Novo Nordisk on the one hand and the RCA PM Parties on the other hand.

(ii) **After the Program Handoff Date**. From and after the Program Handoff Date, as among the Parties, other than with respect to the Licensed Product-Specific Patents (which are addressed in Section 10.4.4), Novo Nordisk shall have the first right, but not the obligation, to Prosecute and Maintain all PM and NN Joint Developed Patents and LNP Joint Patents in the Territory at Novo Nordisk's expense with counsel of its choice. Novo Nordisk shall (i) keep the RCA PM Parties (or after the Program Handoff Date, PlatformCo) informed as to material developments with respect to the Prosecution and Maintenance of such PM and NN Joint Developed Patents and LNP Joint Patents, including by providing copies of all substantive office actions or any other substantive documents that Novo Nordisk receives from any Patent

office, including notice of all interferences, reissues, re-examinations, oppositions or requests for Patent term extensions; and (ii) provide the RCA PM Parties (or after the Program Handoff Date, PlatformCo) with a reasonable opportunity to substantively comment on the Prosecution and Maintenance of such PM and NN Joint Developed Patents and LNP Joint Patents (including the filing of initial applications), and in each case, shall in good faith consider any reasonable comments provided by, and reasonable actions recommended by, the RCA PM Parties (or after the Program Handoff Date, PlatformCo). If, during the Term, Novo Nordisk decides not to Prosecute and Maintain any such PM and NN Joint Developed Patent or LNP Joint Patent, or intends to allow such PM and NN Joint Developed Patent or LNP Joint Patent to lapse or become abandoned without having first filed a substitute, Novo Nordisk shall notify and consult with the RCA PM Parties (or after the Program Handoff Date, PlatformCo) of such decision or intention at least [***] prior to the date upon which the subject matter of such PM and NN Joint Developed Patent or LNP Joint Patent shall become unpatentable or shall lapse or become abandoned, and the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall thereupon have the right (but not the obligation) to assume the Prosecution and Maintenance thereof at the RCA PM Parties' (or after the Program Handoff Date, PlatformCo's) own expense with counsel of their choice. In such event, the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall: (1) provide to Novo Nordisk copies of all substantive office actions or any other substantive documents that the RCA PM Parties (or after the Program Handoff Date, PlatformCo) receive from any Patent office, including notice of all interferences, reissues, re-examinations, oppositions or requests for Patent term extensions, with respect to such PM and NN Joint Developed Patent or LNP Joint Patent; and (2) provide Novo Nordisk with a reasonable opportunity to substantively comment on the Prosecution and Maintenance of such PM and NN Joint Developed Patent or LNP Joint Patent (including the filing of initial applications), and in each case, shall in good faith consider any reasonable comments provided by, and reasonable actions recommended by, Novo Nordisk. Notwithstanding the foregoing, the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall not have the right to assume the Prosecution and Maintenance of such PM and NN Joint Developed Patent or LNP Joint Patent if Novo Nordisk notifies the RCA PM Parties (or after the Program Handoff Date, PlatformCo) that Novo Nordisk in good faith has reasonable grounds for believing that the RCA PM Parties' Prosecution and Maintenance of such PM and NN Joint Developed Patent or LNP Joint Patent pursuant to the foregoing could be reasonably detrimental to any Patent within Novo Nordisk's Background IP, Novo Nordisk Developed IP, PM and NN Joint Developed IP, LNP Joint IP or any Novo Nordisk commercial strategy, as applicable.

10.4.3 **Novo Nordisk Patents**. As among the Parties, Novo Nordisk shall have the sole right, but not the obligation, to Prosecute and Maintain all Patents that are, as among the Parties, solely Controlled by Novo Nordisk in the Territory (including Patents within Novo Nordisk's Background IP and NN Background Improvements) at Novo Nordisk's expense with counsel of its choice.

10.4.4 **Licensed Product-Specific Patents**.

(a) **Background Licensed Product-Specific Patents**. As among the Parties, the RCA PM Parties (or PlatformCo after the Program Handoff Date) shall have the first right, but not the obligation, to Prosecute and Maintain all Licensed Product-Specific Patents within the Background IP ("**Background Licensed Product-Specific Patents**") in the Territory at the RCA PM Parties' (or PlatformCo's after the Program Handoff Date) expense with counsel of their choice. The RCA PM Parties (or PlatformCo after the Program Handoff Date) shall (i) keep Novo Nordisk informed as to material developments with respect to the Prosecution and Maintenance of the Background Licensed Product-Specific Patents, including by providing copies of all substantive office actions or any other substantive documents that PlatformCo receives from any Patent office, including notice of all interferences, reissues, re-examinations, oppositions or requests for Patent term extensions; and (ii) provide Novo Nordisk with a reasonable opportunity to substantively comment on the Prosecution and Maintenance of such Background Licensed Product-Specific Patents (including the filing of initial applications), and in each case, shall in good faith consider any reasonable comments provided by, and reasonable actions recommended by, Novo Nordisk. If, during the Term, the RCA PM Parties (or PlatformCo after the Program Handoff Date) decide not to Prosecute and Maintain any Background Licensed Product-Specific Patent in the Field in a given country in the Territory, or intend to allow such Background Licensed Product-Specific Patent to lapse or become abandoned without having first filed a substitute, the RCA PM Parties (or PlatformCo after the Program Handoff Date) shall notify and consult with Novo Nordisk of such decision or intention at least [***] prior to the date upon which the subject matter of such Background Licensed Product-Specific Patent shall become unpatentable or shall lapse or become abandoned, and Novo Nordisk shall thereupon have the right (but not the obligation) to assume the Prosecution and Maintenance thereof at Novo Nordisk's own expense with counsel of its choice. In such event, Novo Nordisk shall: (1) provide to the RCA PM Parties (or PlatformCo after the Program Handoff Date) copies of all substantive office actions or any other substantive documents that Novo Nordisk receives from any Patent office, including notice of all interferences, reissues, re-examinations, oppositions or requests for Patent term extensions, with respect to such Background Licensed Product-Specific Patent; and (2) provide the RCA PM Parties (or PlatformCo after the Program Handoff Date) with a reasonable opportunity to substantively comment on the Prosecution and Maintenance of such Background Licensed Product-Specific Patents (including the filing of initial applications), and in each case, shall in good faith consider any reasonable comments provided by, and reasonable actions recommended by, the RCA PM Parties (or PlatformCo after the Program Handoff Date). Notwithstanding anything in the foregoing, Novo Nordisk shall not have the right to assume the Prosecution and Maintenance of such Background Licensed Product-Specific Patent if the RCA PM Parties (or PlatformCo after the Program Handoff Date) notify Novo Nordisk that they have in good faith, reasonable grounds for believing that Novo Nordisk's Prosecution and Maintenance of such Background Licensed Product-Specific Patent pursuant to the foregoing could be reasonably detrimental to any Patent within the RCA PM Parties' (or PlatformCo's after the Program Handoff

Date) Background IP, RCA PM Parties Joint Developed IP, PM and NN Joint Developed IP or any RCA PM Party (or PlatformCo after the Program Handoff Date) commercial strategy, as applicable.

(b) **Developed Licensed Product-Specific Patents**. As among the Parties, Novo Nordisk shall have the first right, but not the obligation, to Prosecute and Maintain all Licensed Product-Specific Patents other than the Background Licensed-Product Specific Patents ("**Developed Licensed Product-Specific Patents**"). Novo Nordisk shall (i) keep the RCA PM Parties (or after the Program Handoff Date, PlatformCo) informed as to material developments with respect to the Prosecution and Maintenance of the Developed Licensed-Product Specific Patents, including by providing copies of all substantive office actions or any other substantive documents that Novo Nordisk receives from any Patent office, including notice of all interferences, reissues, re-examinations, oppositions or requests for Patent term extensions; and (ii) provide the RCA PM Parties (or after the Program Handoff Date, PlatformCo) with a reasonable opportunity to substantively comment on the Prosecution and Maintenance of such Developed Licensed-Product Specific Patents (including the filing of initial applications), and in each case, shall in good faith consider any reasonable comments provided by, and reasonable actions recommended by, the RCA PM Parties (or after the Program Handoff Date, PlatformCo). If, during the Term, the Novo Nordisk decides not to Prosecute and Maintain any Developed Licensed-Product Specific Patent, or intends to allow such Developed Licensed-Product Specific Patent to lapse or become abandoned without having first filed a substitute, Novo Nordisk shall notify and consult with the RCA PM Parties (or after the Program Handoff Date, PlatformCo) of such decision or intention at least [***] prior to the date upon which the subject matter of such Developed Licensed-Product Specific Patent shall become unpatentable or shall lapse or become abandoned, and the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall thereupon have the right (but not the obligation) to assume the Prosecution and Maintenance thereof at the RCA PM Parties' (or after the Program Handoff Date, PlatformCo's) own expense with counsel of its choice. In such event, the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall: (1) provide to Novo Nordisk copies of all substantive office actions or any other substantive documents that the RCA PM Parties (or after the Program Handoff Date, PlatformCo) receive from any Patent office, including notice of all interferences, reissues, re-examinations, oppositions or requests for Patent term extensions, with respect to such Developed Licensed-Product Specific Patent; and (2) provide Novo Nordisk with a reasonable opportunity to substantively comment on the Prosecution and Maintenance of such Developed Licensed-Product Specific Patent (including the filing of initial applications), and in each case, shall in good faith consider any reasonable comments provided by, and reasonable actions recommended by, Novo Nordisk. Notwithstanding the foregoing, the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall not have the right to assume the Prosecution and Maintenance of such Developed Licensed-Product Specific Patent if Novo Nordisk notifies the RCA PM Parties that it has in good faith, reasonable grounds for believing that the RCA PM Parties' Prosecution and Maintenance of such Developed Licensed-Product Specific Patent pursuant to the foregoing could be reasonably detrimental to any Patent

within Novo Nordisk's Background IP, Novo Nordisk Developed IP, PM and NN Joint Developed IP or any Novo Nordisk commercial strategy, as applicable.

10.4.5 **Cooperation**. Each Party agrees to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable the Party responsible for the Prosecution and Maintenance of a Patent in accordance with this Section 10.4 to undertake such Prosecution and Maintenance.

10.4.6 **Patent Term Extension**. The Parties shall consult with and cooperate and coordinate with each other in obtaining patent term extensions or supplemental protection certificates and the like with respect to the Licensed Patents as related to Licensed Products, in each country and region where it is possible to do so. As among the Parties, Novo Nordisk shall have the sole right to elect whether to pursue patent term extensions or supplemental protection certificates as related to Licensed Products. Novo Nordisk shall have the right in its sole discretion to pursue (and require that PlatformCo pursue) patent term extensions or supplemental protection certificates with respect to Licensed Product-Specific Patents. The prior written consent of the RCA PM Parties (or PlatformCo following the Program Handoff Date) shall be required for Novo Nordisk to pursue (and require that PlatformCo pursue) patent term extensions or supplemental protection certificates with respect to any Licensed Patent other than Licensed Product-Specific Patents, which consent shall not unreasonably be withheld, conditioned or delayed. The RCA PM Parties (or PlatformCo following the Program Handoff Date) shall provide prompt and reasonable assistance, as requested by Novo Nordisk, at Novo Nordisk's reasonable, cost and expense, including by taking such action as may be required of the Patent holder under any Applicable Laws to obtain such patent term extension or supplementary protection certificate.

10.4.7 **CREATE Act**. The Parties acknowledge and agree that this Agreement is deemed a "joint research agreement" as defined in 35 USC § 100(h). Notwithstanding anything to the contrary in this Article 10, no Party will have the right to provide to a court or an agency a statement under 37 C.F.R. §1.104(c)(4)(ii)(A) to disqualify, for purposes of 35 USC § 102(b)(2)(C) or 35 USC § 102(c), prior art under § 102(a)(2) by the other Parties without the prior written consent of such Party, which will not be unreasonably withheld, conditioned or delayed. With respect to any such permitted statement, the Parties shall coordinate their activities with respect to any submissions, filings, or other activities in support thereof, including the filing of a terminal disclaimer under 37 C.F.R. § 1.321(d) to overcome an obviousness-type double patenting rejection in any patent application Covering a Licensed Product or uses thereof. For the avoidance of doubt, it shall not be considered unreasonable for a Party to withhold written consent with respect to the foregoing if such written consent would allow the filing of a terminal disclaimer that could shorten the Patent term of a Licensed Product-Specific Patent that has been increased due to Patent term adjustment under 35 U.S.C. § 154.

10.4.8 **Certain Licensed Patents**. In the event that any claims of a Licensed Patent could Cover subject matter that could be claimed under either a Licensed Epigenomic Controller Patent or a Licensed Product-Specific Patent, then where practicable under the circumstances, the Parties shall use good-faith efforts to cause such subject matter to be divided among separate Patents, such that any resulting Licensed Epigenomic Controller Patent and Licensed Product-Specific Patent do not both contain claim(s) Covering such subject matter.

10.5 **Enforcement and Defense of Patents**.

10.5.1 **Notice**. If any Party learns of an infringement or threatened infringement by a Third Party with respect to any Licensed Patent in the Field in the Territory, or of any claim of invalidity, unenforceability, or non-infringement of any Licensed Patent (and can disclose same without violating any Third Party obligations) such Party shall promptly notify the other Parties and shall provide the other Parties with available evidence of such infringement in such Party's possession or control.

10.5.2 **General Licensed Patents; Licensed Epigenomic Controller Patents**. As among the Parties, other than with respect to Joint Patents (which are addressed in Sections 10.5.4 and 10.5.5), PM SpinCo (Novo Nordisk after the Program Handoff Date) shall have the sole and exclusive right, but not the obligation, to institute, prosecute and control any Action with respect to any infringement of any General PM SpinCo Licensed Patents in the Territory, by counsel of its own choice. As among the Parties, other than with respect to Joint Patents (which are addressed in Sections 10.5.4 and 10.5.5), PlatformCo shall have the sole and exclusive right, but not the obligation, to institute, prosecute and control any Action with respect to any infringement of any General PlatformCo Licensed Patents and Licensed Epigenomic Controller Patents in the Territory, by counsel of its own choice; *provided, however*, that notwithstanding the foregoing, [***].

10.5.3 **Novo Nordisk Patents**. As among the Parties, Novo Nordisk shall have the sole and exclusive right, but not the obligation, to institute, prosecute and control any Action with respect to any infringement of any Patents that are solely Controlled, as among the Parties, by Novo Nordisk in the Territory (including Patents within the NN Background Improvements), by counsel of its own choice.

10.5.4 **PM and NN Joint Developed Patents and LNP Joint Patents**.

(a) **Competitive Infringement**. As among the Parties, other than with respect to the Licensed Product-Specific Patents (which are addressed in Section 10.5.6), Novo Nordisk shall have the sole and exclusive right, but not the obligation, to institute, prosecute and control any Competitive Infringement Action with respect to any infringement of any PM and NN Joint Developed Patents and LNP Joint Patents in the Territory in the Field.

(b) **Actions Other Than Competitive Infringement**. As among the Parties, other than with respect to the Licensed Product-Specific Patents (which are addressed in Section 10.5.6), Novo Nordisk on the one hand and the RCA PM Parties (or after the Program Handoff Date, PlatformCo) have the right, but not the obligation, to jointly institute, prosecute and control any Action with respect to any infringement of any PM and NN Joint Developed Patents and LNP Joint Patents in the Territory that is not Competitive Infringement. Notwithstanding the foregoing, (a) prior to the Program Handoff Date, decisions regarding such Actions (including whether to commence, continue or settle such Action) will be made by the Parties through the JPC and (b) from and after the Program Handoff Date, decisions regarding such Actions (including whether to commence, continue or settle such Action) will require the mutual written agreement of Novo Nordisk and PlatformCo. Expenses for such Action shall be shared equally by Novo Nordisk on the one hand and the RCA PM Parties on the other hand.

10.5.5 **RCA PM Parties Joint Developed Patents**. As among the Parties, other than with respect to Licensed Product-Specific Patents (which are addressed in Section 10.5.6), the RCA PM Parties (or after the Program Handoff Date, PlatformCo) shall have the sole and exclusive right, but not the obligation, to institute, prosecute and control any Action with respect to any infringement of any RCA PM Parties Joint Developed Patents in the Territory, and to defend the RCA PM Parties Joint Developed Patents in the Territory from any Action of invalidity or unenforceability, in each case, by counsel of their own choice.

10.5.6 **Licensed Product-Specific Patents**.

(a) **Prior to** [***]. Prior to the [***]:

(i) **Enforcement and Defense**. As among the Parties, the RCA PM Parties shall have the sole and exclusive right, but not the obligation, to institute, prosecute and control any Action with respect to any infringement of any Licensed Product-Specific Patents in the Territory; *provided*, that (a) the RCA PM Parties shall inform Novo Nordisk in writing of any proposed Action prior to commencement thereof and (b) commencement of any such Action by the RCA PM Parties shall require mutual agreement of the RCA PM Parties and Novo Nordisk. The RCA PM Parties shall keep Novo Nordisk reasonably informed of material developments with respect to any Action instituted, prosecuted or controlled under this Section 10.5.6(a) (including by notifying Novo Nordisk of any decision to settle any such Action) and use Commercially Reasonable Efforts to implement any reasonable comments from Novo Nordisk in respect thereto.

(ii) **Settlement**. The RCA PM Parties may settle any claim, suit or action that it brought under this Section 10.5.6(a); *provided*, *however*, that the consent of Novo Nordisk shall be required if such settlement includes the grant of any license, covenant or other rights to any Licensed Product-Specific Patents to any Third Party that would conflict with or reduce the scope of the subject matter included under any rights granted (or contemplated to be granted) to Novo Nordisk pursuant to this Agreement.

(b) **After the** [***]. From and after the [***]:

(i) **Novo Nordisk First Right**. As among the Parties, Novo Nordisk shall have the first right, but not the obligation, using counsel of its choosing and at its sole expense, to institute any Competitive Infringement Action alleging Competitive Infringement of the Licensed Product-Specific Patents by a Third Party. Novo Nordisk shall notify and keep PlatformCo reasonably apprised in writing of any such Competitive Infringement Action and shall consider PlatformCo's reasonable interests and requests regarding such Competitive Infringement Action.

(ii) **PlatformCo Right**. Novo Nordisk shall notify PlatformCo of its decision to commence a Competitive Infringement Action with respect to the Licensed Product-Specific Patents (or to settle a Competitive Infringement Action or otherwise secure the abatement of the applicable Competitive Infringement). If Novo Nordisk fails to bring or defend such Competitive Infringement Action or otherwise take action to abate such Competitive Infringement (i) within [***] after its receipt or delivery of notice under Section 10.5.1, or (ii) *provided* such date occurs after the first such notice of the Competitive Infringement is provided, at least [***] before the time limit, if any, set forth in the Applicable Laws for the filing of such Actions, whichever comes first, then PlatformCo shall have the right, but not the obligation, at its own expense to institute such Competitive Infringement Action against the applicable Third Party infringer(s); *provided* that PlatformCo shall have no right to bring such Competitive Infringement Action if Novo Nordisk's election not to bring such Competitive Infringement Action is based on good faith, reasonable grounds for believing that bringing such Competitive Infringement Action pursuant to the foregoing could be reasonably detrimental to any Patent within Novo Nordisk's Background IP, Novo Nordisk Developed IP, PM and NN Joint Developed IP, Licensed Patents or any Novo Nordisk commercial strategy, as applicable.

(iii) **Settlement**. Neither PlatformCo nor Novo Nordisk shall settle or consent to an adverse judgment in any action described in this Section 10.5.6(b) and controlled by the other Party, including any judgment which affects the scope, validity or enforcement of Licensed Product-Specific Patents involved therewith, without the prior written consent of the other (such consent not to be unreasonably withheld or delayed).

10.5.7 **Cooperation, Expenses and Recoveries**.

(a) **Cooperation**. In any Action brought under or with respect to the PM and NN Joint Developed Patents or Licensed Product-Specific Patents pursuant to Section 10.5.4 or 10.5.6, each Party shall, and shall cause its Affiliates to, reasonably cooperate with each other, in good faith, relative to the other Party's efforts to protect such Patents, including, at such other Party's cost and expense, by joining such action as a party plaintiff if required by Applicable Laws to pursue such action. Furthermore, the Controlling Party shall consider in good faith all reasonable and timely comments from the other Party on any proposed arguments asserted or to

be asserted in such Action. Neither Party shall have the right to settle any Action with respect to any PM and NN Joint Developed Patent or Licensed Product-Specific Patent under Section 10.5.4 or 10.5.6 in a manner that imposes any costs or liability on, or involves any admission by, the other Party without the consent of such other Party (which shall not be unreasonably withheld, conditioned, or delayed).

(b) **Expenses**. Subject to Sections 10.5.7(a) and 10.5.7(c), each Party shall be solely responsible for all of its expenses arising from an Action brought pursuant to Section 10.5.4 or 10.5.6. For the avoidance of doubt, the Controlling Party shall not be responsible for the other Party's internal expenses (e.g., FTEs) incurred as a result of the other Party's cooperation with the Action as provided in Section 10.5.7(a). The non-Controlling Party with respect to an Action shall be entitled to participate in such Action with separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such Action.

(c) **Allocation of Recoveries**. Any settlements, damages or monetary awards recovered by a Party pursuant to any Action brought pursuant to Section 10.5.4 or 10.5.6 shall, after reimbursing the Parties for their reasonable expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses), be [***]; *provided*, that if Novo Nordisk is the Controlling Party, such amounts shall [***].

10.5.8 **Patent Invalidity Claim**. If a Third Party at any time asserts a counterclaim to a patent infringement claim initiated by a Party that any Licensed Patent or Joint Patent that Covers a Licensed Product in the Field is invalid or otherwise unenforceable (an "**Invalidity Claim**"), control of the response to such Invalidity Claim shall, as among the Parties, be determined in the same manner as enforcement rights with respect to such Patents are determined pursuant to Section 10.5, and the non-Controlling Party shall cooperate with the Controlling Party in the preparation and formulation of such response, and in taking other steps reasonably necessary to respond, to such Invalidity Claim. Neither Party shall settle or compromise any Invalidity Claim without the consent of the other Party, which consent shall not be unreasonably withheld. If the Invalidity Claim does not arise in connection with a suit or action referred to in this Section 10.5, Control of and the costs and expenses of responding to the Invalidity Claim shall be borne by the Party responsible for Prosecuting and Maintaining the applicable Patent in accordance with Section 10.4.

10.6 **Defense of Claims Brought by Third Parties**. The Parties shall each promptly notify the other if a Third Party brings any Action against any of them alleging patent infringement by a Party or any of its respective Affiliates or sublicensees (including Sublicensees) with respect to the Development, Manufacture or Commercialization of any Licensed Product (any such Action, an "**Infringement Claim**") in the Territory, and the Parties shall each promptly confer to consider the claim or assertion and the appropriate course of action. Each Party (itself or through its sublicensee (including Sublicensee)) shall have the sole right, but not the obligation, to control

the defense and response to any such Infringement Claim in the Territory naming such Party or its Affiliate or its sublicensee (including Sublicensee) as a defendant, at such Party's or its sublicensee's (including its Sublicensee's) sole cost and expense, and the other Parties (itself or through its sublicensees (including Sublicensees)) shall have the right, at its own expense, to be represented in any such Infringement Claim in the Territory by counsel of their own choice. Upon the request and at the expense of the Party controlling the response to the Infringement Claim, the other Parties shall reasonably cooperate with the controlling Party in the reasonable defense of such Infringement Claim. If the Infringement Claim is brought against two or more Parties, then such Parties shall each have the right to defend against the Infringement Claim. The Party defending an Infringement Claim under this Section 10.6 shall (a) consult with the other Parties as to the strategy for the prosecution of such defense, (b) consider in good faith any comments from the other Parties with respect thereto, and (c) keep the other Parties reasonably informed of any material steps taken and provide copies of all material documents filed in connection with such defense. The Party controlling the defense against an Infringement Claim shall have the right to settle such Infringement Claim on terms deemed reasonably appropriate by such Party, *provided* that no Party shall have the right to settle any Infringement Claim in a manner that imposes any costs or liability on, or involves any admission by, the other Parties without the consent of such other Parties (which shall not be unreasonably withheld, conditioned, or delayed).

10.7 **Patent Marking**. Novo Nordisk shall mark, and shall cause all of its Affiliates and Sublicensees to mark, Licensed Products with all Licensed Patents in accordance with Applicable Laws, which marking obligation shall continue to the extent and for as long as required under Applicable Laws. Pursuant to the FPIV License, Novo Nordisk agrees to permanently and legibly mark all Licensed Products (as defined in the FPIV License) made, used, reproduced, or sold under the terms of this Agreement, or their respective containers, in accordance with the applicable provisions set forth in the Patent marking and notice provisions under Title 35 of the United States Code.

10.8 **Common Interest Disclosures**. With regard to any information or opinions disclosed pursuant to this Article 10 by one Party to the other Parties regarding Prosecution and Maintenance of the Licensed IP, or enforcement of Intellectual Property or technology by or against Third Parties, the Parties agree that they have a common legal interest in determining the ownership, scope, validity and enforcement of Licensed IP, and whether, and to what extent, Third Party Intellectual Property rights may affect the conduct of the Development, Manufacture and Commercialization of any Licensed Product, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of Intellectual Property rights relating to the research, Development, Manufacturing, or Commercialization of any Licensed Product. Accordingly, the Parties agree that all such information and materials obtained by the Parties from each other shall be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All such information and materials shall be treated as protected by the attorney-client privilege, the work

product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, no Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. No Party shall have the authority to waive any privilege or immunity on behalf of the other Parties without such other Parties' prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against the other Parties.

10.9 **Upstream Licenses**. To the extent that an Upstream Licensor of PlatformCo has retained any right to prosecute or enforce any PlatformCo Licensed Patents or otherwise be involved in such activities pursuant to the Upstream Licenses granting PlatformCo a license thereto, PlatformCo shall use reasonable efforts to cause such Upstream Licensor to take the actions (or refrain from taking action, as applicable) consistent with this Article 10. [***].

10.10 **In-Licenses**.

10.10.1 **Upstream Licenses**. Except as set forth in Section 10.10.2, as among the Parties, PlatformCo shall be responsible for all payments associated with any Upstream Licenses ("**Upstream License Costs**"). Without limiting the foregoing, if PlatformCo fails to pay Upstream License Costs or otherwise fails to maintain the Upstream Licenses as required by Section 9.4.3 and Novo Nordisk pays such Upstream License Costs on PlatformCo's behalf or otherwise incurs any costs in connection with maintaining such Upstream Licenses, including without limitation costs associated with securing and maintaining a replacement agreement if PlatformCo allows any such Upstream License to terminate or expire in violation of Section 9.4.3, then Novo Nordisk shall be entitled to offset any such costs from any payments due to PlatformCo hereunder, [***]. The offsets in this Section 10.10.1 are intended to be additive with the offsets regarding Upstream License Costs in the Share Purchase Agreement and the Option Agreement, and nothing in this Agreement shall prevent Novo Nordisk from taking offsets under this Section 10.10.1 as well as the foregoing offsets in the Share Purchase Agreement and the Option Agreement to the extent otherwise applicable.

10.10.2 **New In-Licenses**.

(a) **Generally**. Subject to this Section 10.10.2, if during the Term, a Party identifies any Third Party Patents or Know-How that would be necessary or reasonably useful for the Parties' performance of activities set forth in the R&D Plan or for the Exploitation of the IND-Enabling Candidate or Licensed Products, in each case, pursuant to the terms of this Agreement, such Party may independently negotiate and enter into an agreement to obtain a license or other rights to such Patents or Know-How for use in connection with the performance of such R&D Plan activities or the Exploitation of the IND-Enabling Candidate or Licensed Products, in each case pursuant to the terms of this Agreement (a "**New In-License**").

(b) **Core IP**.

(i) **Negotiation Responsibility**. Notwithstanding Section 10.10.2(a), if a Party identifies any Core Patents or Core Know-How owned or Controlled by a Third Party, including a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, such Party shall promptly notify PlatformCo of such Core Patents or Core Know-How, and PlatformCo shall negotiate for and use good faith efforts to enter into a New In-License with respect to such Core Patents or Core Know-How. PlatformCo shall keep Novo Nordisk reasonably apprised of the negotiations of such license, including by providing copies of any draft agreements received from or sent to such Third Party, and PlatformCo shall reasonably consider any comments or requests provided by Novo Nordisk. PlatformCo shall not agree to terms that disproportionately allocate any amounts payable to such Third Party with respect to the IND-Enabling Candidate, Licensed Products or Novo Nordisk's rights hereunder (e.g., the upfront payments, milestone payments, royalty for product sales and other payments shall be fairly allocated based on the extent to which such amounts are attributable to the IND-Enabling Candidate and Licensed Product(s), and taking into account exploitation of the Core Patents and Core Know-How by PlatformCo for other purposes). If PlatformCo enters into a New In-License with respect to such Core Patents or Core Know-How pursuant to this Section 10.10.2(b)(i), then, *provided* Novo Nordisk agrees to comply with any obligations under such New In-License that apply to Novo Nordisk as a sublicensee thereunder, such Core Patents and Core Know-How shall be deemed PlatformCo Licensed Patents or PlatformCo Licensed Know-How, as applicable, subject to the terms and conditions of this Agreement and the applicable New In-License shall be deemed an Upstream License hereunder. If Novo Nordisk does not agree to comply with such obligations, then: (A) such Core Patents and Core Know-How, as applicable, shall not be deemed "Controlled" by PlatformCo for purposes of this Agreement and shall be excluded from the PlatformCo Licensed Patents or PlatformCo Licensed Know-How, as applicable; and (B) Novo Nordisk shall have no right or license under such Core Patents and Core Know-How or any financial obligations with respect thereto; and (C) PlatformCo shall have the right to terminate or cease negotiations for a license to such Core Patent(s) and Core Know-How.

(ii) **Financial Responsibility**.

(A) **Affiliate Core IP and PlatformCo In-Licensed Known Third Party Core IP**. If Novo Nordisk accepts a sublicense under a New In-License with respect to any Core IP pursuant to Section 10.10.2(b)(i) and such Core IP constitutes Affiliate Core IP or PlatformCo In-Licensed Known Third Party Core IP, then [***] shall be responsible for all payments to the applicable Third Party in connection with such New In-License, [***].

(B) **PlatformCo In-Licensed Unknown Third Party Core IP**. If Novo Nordisk accepts a sublicense under a New In-License with respect to any Core IP pursuant to Section 10.10.2(b)(i) and such Core IP constitutes PlatformCo In-Licensed Unknown Third Party Core IP, then Novo Nordisk shall be responsible for, and shall pay to PlatformCo, all payments that would be due to the Upstream Licensor under such New In-License

as a result of Novo Nordisk's exercise of its rights under this Agreement (including an equitably prorated portion of non-royalty payments under such New In-License), and Novo Nordisk shall be entitled to deduct [***] of such payments against any [***] otherwise due to PlatformCo under this Agreement; *provided*, *however*, that in no event shall such deductions under this Section 10.10.2(b)(ii)(B) in aggregate reduce any [***] to less than the Payment Reduction Floor. The offsets in this Section 10.10.2(b)(ii)(B) are intended to be additive with the offsets regarding PlatformCo In-Licensed Unknown Third Party Core IP in the Share Purchase Agreement and the Option Agreement, and nothing in this Agreement shall prevent Novo Nordisk from taking offsets under this Section 10.10.2(b)(ii)(B) as well as the foregoing offsets in the Share Purchase Agreement and the Option Agreement to the extent otherwise applicable.

(iii) **Novo Nordisk Step-In Rights**. If PlatformCo does not enter into such New In-License with respect to any Core IP within [***] after receipt of notice under Section 10.10.2(b)(i) (or such earlier time as PlatformCo notifies Novo Nordisk that PlatformCo is unlikely to enter into such New In-License despite PlatformCo's Commercially Reasonable Efforts), then Novo Nordisk shall have the right to negotiate for and enter into such New In-License and PlatformCo's failure to enter into such New In-License shall not constitute a breach of this Agreement, *provided* that PlatformCo has used Commercially Reasonable Efforts to enter into such New In-License. If Novo Nordisk subsequently enters into a New In-License with respect to such Core IP and such Core IP constitutes: (A) NN Flagship Known Third Party Core IP, then Novo Nordisk shall be responsible for all payments associated with the license between Novo Nordisk and the applicable Third Party in connection with such NN Flagship Known Third Party Core IP, and Novo Nordisk shall be entitled to deduct [***] of such payments against [***] otherwise due to PlatformCo under this Agreement (including an equitably prorated portion of non-royalty payments under such New In-License) and such deduction under this Section 10.10.2(b)(iii)(A) shall [***]; or (B) NN Unknown Third Party Core IP, then Novo Nordisk shall be responsible for all payments associated with the license between Novo Nordisk and the applicable Third Party in connection with such NN Unknown Third Party Core IP, and Novo Nordisk shall be entitled to deduct [***] of such payments against [***] otherwise due to PlatformCo under this Agreement (including an equitably prorated portion of non-royalty payments under such New In-License); *provided*, *however*, that in no event shall such deductions under this Section 10.10.2(b)(iii)(B) in aggregate reduce [***] to [***]. The offsets in this Section 10.10.2(b)(iii) are intended to be additive with the offsets regarding NN Flagship Known Third Party Core IP and NN Unknown Third Party Core IP, as applicable, in the Share Purchase Agreement and the Option Agreement, and nothing in this Agreement shall prevent Novo Nordisk from taking offsets under this Section 10.10.2(b)(iii) as well as the foregoing offsets in the Share Purchase Agreement and the Option Agreement to the extent otherwise applicable.

(c) **Other New PM Party IP**.

(i) **In General**. Following the Effective Date, (A) PlatformCo or any of its Subsidiaries shall have the right to enter into New In-Licenses for Other New PM Party IP (subject to Section 10.10.2(c)(iv), including with respect to the Program Tissue LNP) and (B) prior to the Program Handoff Date, PM SpinCo shall not enter into New In-Licenses for Other New PM Party IP except with the prior written consent of Novo Nordisk subject in each case ((A) and (B)) to this Section 10.10.2(c). For the avoidance of doubt, nothing in this Section 10.10.2(c) shall limit Novo Nordisk's ability to enter into in-license agreements for Other New IP (in which case, Section 8.5.4(a)(i) will apply).

(ii) **Negotiation Responsibility**. If PlatformCo determines to enter into a New In-Licenses for Other New PM Party IP or if Novo Nordisk consents to PM SpinCo's entry into a New In-Licenses for Other New PM Party IP, then the applicable RCA PM Party shall (A) so inform Novo Nordisk, (B) keep Novo Nordisk reasonably apprised of the negotiations of such license, including by providing copies of any draft agreements received from or sent to such Third Party, and (C) shall reasonably consider any comments or requests provided by Novo Nordisk. The applicable RCA PM Party shall not agree to terms that disproportionately allocate any amounts payable to such Third Party with respect to the IND-Enabling Candidate, Licensed Products or Novo Nordisk's rights hereunder (e.g., the upfront payments, milestone payments, royalty for product sales and other payments shall be fairly allocated based on the extent to which such amounts are attributable to the applicable the IND-Enabling Candidate and Licensed Product(s) and taking into account exploitation of the Core Patents and Core Know-How by the applicable RCA PM Party for other purposes). If an RCA PM Party enter into such New In-License for Other New PM Party IP, then, *provided* Novo Nordisk agrees to comply with any obligations under such New In-License that apply to Novo Nordisk as a sublicensee thereunder, such Other New PM Party IP shall be deemed Licensed Patents or Licensed Know-How, as applicable, subject to the terms and conditions of this Agreement, and the applicable New In-License shall be deemed an Upstream License hereunder. If Novo Nordisk does not agree to comply with any obligations under such New In-License that apply to Novo Nordisk or make such payments, such Other New PM Party IP shall not be deemed "Controlled" by the applicable RCA PM Party for the purposes of this Agreement and shall be excluded from the Licensed Patents or PlatformCo Licensed Know-How, as applicable, and Novo Nordisk shall have no right or license under such Other New PM Party IP or any financial obligations with respect thereto.

(iii) **Financial Responsibility**. If Novo Nordisk accepts a sublicense under a New In-License for Other New PM Party IP pursuant to Section 10.10.2(c)(ii), then Novo Nordisk shall be responsible for, and shall pay to PlatformCo or PM SpinCo, as applicable, all payments that would be due to the Upstream Licensor under such New In-License as a result of Novo Nordisk's exercise of its rights under this Agreement (including an equitably prorated portion of non-royalty payments under such New In-License). Novo Nordisk shall be entitled to deduct [***] of such payments against [***] otherwise due to PlatformCo under this Agreement; *provided*, *however*, that in no event shall such deductions under this Section

10.10.2(c)(iii) in aggregate reduce any [***] to less than [***]. The offsets in this Section 10.10.2(c)(iii) are intended to be additive with the offsets regarding Other New PM Party IP in the Share Purchase Agreement and the Option Agreement, and nothing in this Agreement shall prevent Novo Nordisk from taking offsets under this Section 10.10.2(c)(iii) as well as the foregoing offsets in the Share Purchase Agreement and the Option Agreement to the extent otherwise applicable.

(iv) **Program Tissue LNP**.

(A) Notwithstanding anything to the contrary in this Section 10.10.2(c) above, if any Party identifies any Patents or Know-How Controlled by a Third Party that such Party believes are necessary or reasonably useful for the Parties' performance of R&D Activities set forth in the R&D Plan with respect to the Development of the Program Tissue LNP (or any component thereof) or for the Exploitation of the IND-Enabling Candidate or Licensed Products, then such Party shall promptly notify the other Parties. Promptly upon such notification, the JSC shall meet to determine whether to seek a license to such Patents or Know-How and, if so, which Party shall negotiate for such license. If the JSC determines that PlatformCo will obtain the license to such Patents or Know-How, then PlatformCo shall negotiate for and use Commercially Reasonable Efforts to enter into a New In-License with respect to such Patents or Know-How (and Sections 10.10.2(c)(ii) and 10.10.2(c)(iii) shall apply). If PlatformCo does not enter into such New In-License within [***] after the JSC's determination to seek a license pursuant to this Section 10.10.2(c)(iv) (or such earlier time as PlatformCo notifies Novo Nordisk that PlatformCo is unlikely to enter into such New In-License despite PlatformCo's Commercially Reasonable Efforts), then Novo Nordisk shall have the right to negotiate for and enter into such New In-License and PlatformCo's failure to enter into such New In-License shall not constitute a breach of this Agreement, *provided* that PlatformCo has used Commercially Reasonable Efforts to enter into such New In-License. If the JSC determines that Novo Nordisk will obtain the license to such Patents or Know-How, then Novo Nordisk shall use Commercially Reasonable Efforts to enter into a New In-License with respect to such Patents or Know-How (and Section 8.5.4(a)(i)(B) shall apply). Novo Nordisk's failure to enter into such New In-License shall not constitute a breach of this Agreement, *provided* that Novo Nordisk has used Commercially Reasonable Efforts to enter into such New In-License.

(B) Nothing in this Section 10.10.2(c)(iv) shall prevent Novo Nordisk from Developing or acquiring (including through a license from a Third Party) any LNPs for use in any Novo Nordisk product or program, in which case, Novo Nordisk may elect to use such LNPs for the Development of the Development Candidate, in its sole discretion. If the Parties utilize a Novo Nordisk Controlled LNP in the performance of the Parties' R&D Activities under the R&D Plan, then Novo Nordisk shall be responsible for all payments due to its Third Party licensors under any applicable in-license agreement with respect to such use and the Exploitation of Licensed Products hereunder, and shall be entitled to deduct [***] of such payments against [***] otherwise due to PlatformCo under this Agreement; *provided*, *however*,

that in no event shall such deductions under this Section 10.10.2(c)(iv) in aggregate reduce [***] to [***]. The offsets in this Section 10.10.2(c)(iv) are intended to be additive with the offsets regarding Novo Nordisk Controlled LNPs in the Share Purchase Agreement and the Option Agreement, and nothing in this Agreement shall prevent Novo Nordisk from taking offsets under this Section 10.10.2(c)(iv) as well as the foregoing offsets in the Share Purchase Agreement and the Option Agreement to the extent otherwise applicable.

10.11 **Joint Patent Committee**. Within thirty (30) days after the Effective Date, the Parties will form a joint patent committee (the "**JPC**"), a subcommittee of the JSC that reports to the JSC. The JPC will be composed of an equal number of representatives of each Party (with the exact number of representatives as the Parties may mutually agree), with each representative having appropriate expertise, seniority, decision-making authority and ongoing familiarity with the collaboration under this Agreement, and each Party's representatives collectively will have relevant expertise in intellectual property portfolio management and licensing matters. Each Party may change its representatives to the JPC from time to time in its sole discretion, effective upon written notice to the other Party of such change. The JPC shall (a) evaluate the JPC Evaluated Patents and provide input regarding the strategy of Prosecution and Maintenance and enforcement of JPC Evaluated Patents in accordance with Sections 10.4.2(b) and 10.5.4(b), (b) facilitate information sharing and cooperation among the Parties with respect to the JPC Evaluated Patents and (c) address any other Patent-related matters for which the Parties are obligated to cooperate. Unless otherwise agreed by the Parties, the JPC will have no further responsibilities and will disband at the earlier of (x) the Program Handoff Date or (y) end of the Term. Other than as set forth herein, in order to make any decision required of it hereunder, the JPC must have present (in person, by videoconference or telephonically) at least one member of each Party. The Parties will endeavor to make decisions of the JPC by consensus, *provided* that no decision may be in conflict with any of the terms of this Agreement including the decision rights assigned, as among the Parties, related to patent matters. The JPC will solely have the roles and responsibilities assigned to it in this Section 10.11 or as otherwise specifically provided in this Agreement, and the JPC will have no authority to amend, modify or waive compliance with this Agreement. For purposes of this Section 10.11, "**JPC Evaluated Patents**" shall include the Joint Patents and Licensed Product-Specific Patents.

10.12 **New PlatformCo Patents**. PlatformCo shall disclose to Novo Nordisk any New PlatformCo Patent [***] after PlatformCo determines that [***] for the Exploitation of the IND-Enabling Candidate or Licensed Products in the Field in the Territory, and upon such New PlatformCo Patent issuing in the Territory after such initial notice to Novo Nordisk, PlatformCo shall provide [***] written notice of such issuance to Novo Nordisk. Novo Nordisk may elect to [***].

11. CONFIDENTIALITY AND PUBLICITY.

11.1 **Confidential Information**.

11.1.1 **Confidentiality Obligations**. During the Term and for a period of [***] after any termination or expiration of this Agreement, each Party (including Shareholder, Pioneering Medicines and PMCo) agrees to, and shall cause its Affiliates and require its sublicensees (including Sublicensees) and independent contractors to, (a) keep in confidence and not disclose to any Third Party, (b) not use for any purpose except to exercise its rights or perform its obligations under this Agreement, in each case (a) and (b), or as otherwise permitted in this Agreement, any Confidential Information of the other Parties, without the prior written consent of the disclosing Party.

11.1.2 **Permitted Disclosures**. Each receiving Party agrees that it shall provide or permit access to the other Parties' Confidential Information only to such receiving Party's and its Affiliates' employees, consultants, subcontractors, advisors, and sublicensees (including Sublicensees) (collectively, "**Representatives**"), in each case, on a need to know basis and *provided* that any such Representative is subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Parties pursuant to this Section 11.1 (but of duration customary in confidentiality agreements entered into for a similar purpose); *provided*, *however*, that each Party shall remain responsible for any failure by its Representatives to treat such Confidential Information as required under this Section 11.1 as if such Representatives were parties directly bound to the requirements of this Section 11.1.

11.1.3 **Confidentiality Limitation**. Notwithstanding anything to the contrary herein, each Party may use and disclose the other Parties' Confidential Information (as applicable) as follows: (a) to its financial advisors, attorneys and accountants and underwriters, in each case on a need to know basis and under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose); *provided*, *however*, that each Party shall remain responsible for any failure by any of the foregoing individuals to treat such Confidential Information as required under this Section 11.1 as if such individuals were parties directly bound to the requirements of this Section 11.1, (b) as required by any court or other governmental body or as otherwise required by Applicable Laws (including, solely with respect to the terms of this Agreement, any such disclosures as are required by the rules or regulations of the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States or of any stock exchange or listing entity); *provided* that, notice is promptly given to the disclosing Party and the receiving Party cooperates with reasonable requests from the disclosing Party to assist the disclosing Party's efforts to seek a protective order or other appropriate remedy to protect its Confidential Information or (c) as reasonably necessary in connection with the prosecution of any Patents in accordance with the terms of this Agreement or in connection with seeking authorization to conduct any Clinical Trial, Regulatory Approval, Pricing and Reimbursement Approval or import authorization, in each case, for any Licensed Product in the Territory in accordance with the terms of this Agreement. In

addition, (1) each Party may disclose the terms of this Agreement to its bona fide actual or potential acquisition partners, financing sources or private investors, in each case on a need to know basis and under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose), (2) Novo Nordisk may disclose (A) the terms of this Agreement to its bona fide potential or actual collaborators, licensors, Sublicensees, licensees, or strategic partners and to employees, directors, agents, consultants, and advisers of such entities and (B) (i) the other Parties' Confidential Information to [***] and (ii) [***] and (3) Novo Nordisk may make public disclosures of [***]. Notwithstanding anything to the contrary contained in this Article 11, Confidential Information that is permitted or required to be disclosed shall remain otherwise subject to the confidentiality and non-use provisions of this Section 11.1. If a Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or equivalent foreign agency in a country other than the United States, then such Party shall, a reasonable time (and in no event less than [***]) prior to any such filing, provide the other Parties with a copy of the Agreement showing any provisions hereof as to which the Party proposes to request redaction, shall provide the other Parties with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and shall take such Party's reasonable comments into consideration before filing such agreement and use reasonable efforts to have terms identified by such other Party redacted by the applicable agency, to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

11.2 **Publicity**.

11.2.1 **Public Disclosures in General**. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding any Development Candidates, the IND-Enabling Candidate and Licensed Product in the Field in the Territory, and each Party may make such disclosures from time to time, subject to the terms and conditions of this Agreement, including this Section 11.2. Such disclosures may include achievement of milestones, significant events in the Development process with respect to any Development Candidates, the IND-Enabling Candidate and Licensed Products, or Commercialization activities with respect to Development Candidates, the IND-Enabling Candidate and Licensed Products.

11.2.2 **Press Release; Notification; Review and Comment**. At a mutually agreed upon time following execution of this Agreement, the Parties shall issue a joint press release announcing, *inter alia*, the existence of this Agreement, *provided* that such press release has been reviewed and approved by the Parties, and such joint press release shall be distributed over wire by Novo Nordisk, and concurrently with such press release, PlatformCo shall issue a press release in the form set forth in Schedule 11.2.2, and such PlatformCo press release may be disseminated by PlatformCo by any means except wire distribution (collectively, the "**Press Releases**"). Except

for the Press Releases or for disclosures permitted in accordance with Section 11.1 or 11.3, no Party shall make any public disclosure regarding this Agreement, including any milestones, significant events in the Development or the Commercialization of any Development Candidates, the IND-Enabling Candidate or the Licensed Products in the Territory without first complying with this Section 11.2.2. The Party proposing to make such disclosure shall first notify the other Party(ies) of such planned press release or public announcement and provide a draft for review and seek the other Parties' consent thereof no less than [***] in advance of issuing such press release or making such public announcement (unless, with respect to press releases and public announcements that are required by Applicable Laws, if it is not possible to provide notice at least [***] in advance, in which case such Party shall provide as much advance notice as possible under the circumstances). Each other Party shall have the right to review and comment on any such planned press release or public announcement proposed by any of the other Parties; *provided*, *however*, that the reviewing Party shall attempt to provide comments, if any, as soon as reasonably possible, but in any event within [***] after its receipt thereof. Without limiting the foregoing, the Party desiring to make such public disclosure shall consider in good faith any timely comments of the reviewing Party and, if requested, remove the reviewing Party's Confidential Information from such public disclosure. Notwithstanding the foregoing, a Party desiring to make such public disclosure may issue such press release or public announcement without prior review or consent by the other Parties if (i) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by such Party, and (ii) such press release or public announcement is consistent with the previously issued press release or other publicly available information.

11.2.3 **Disclosures Required by Applicable Laws**. Each Party shall have the right to review, but not approve, any press release or public announcement that the proposing Party determines is required by Applicable Laws based on the advice of counsel, which public disclosures are subject to this Section 11.2.3. The principles to be observed in such disclosures shall include accuracy, compliance with Applicable Laws and regulatory guidance documents, reasonable sensitivity to potential negative reactions of Regulatory Authorities, the desirability to obtain Patents where applicable and the need to keep investors informed regarding the business of the Party making such public disclosure. Nothing in this Section 11.2.3 shall restrict a Party from making a disclosure required by Applicable Laws as reasonably determined by such Party's counsel, including disclosures required by any Applicable Laws relating to the public sale of securities (as provided in Section 11.1.3); *provided*, *however*, that such disclosure shall not include more than the minimum amount of Confidential Information required by such Applicable Laws, and the Parties shall use reasonable efforts to seek confidential treatment of Confidential Information to be included in such disclosures.

11.3 **Publications**.

11.3.1 **Review for Confidential Information and Patentability**. In the event that, (a) [***], Novo Nordisk proposes to publish or present the results of [***], including any oral presentation or abstract, that contains [***] of the IND-Enabling Candidate or Licensed Product or (b) [***], Novo Nordisk proposes to (i) publish or present information for [***] about, and that [***] to, the Program Epigenomic Controller or (ii) publish or present information that [***] to [***] Collaboration Epigenomic Controllers other than the Program Epigenomic Controller [***], then (x) such publication or presentation shall be subject to the prior review by PlatformCo for patentability and protection of PlatformCo's Confidential Information, and (y) Novo Nordisk shall provide to the RCA PM Parties (or after the Closing Date, PlatformCo) the opportunity to review any such proposed publication or presentation at least [***] prior to publication of any article or [***] prior to any oral presentation or abstract. Each RCA PM Party (or after the Closing Date, PlatformCo) may respond in writing promptly (and in no event less than [***] prior to any publication deadline or [***] for oral presentation or abstracts) with a request to remove from such proposed publication or presentation any Confidential Information of the such RCA PM Party (or after the Closing Date, PlatformCo) or a request that Novo Nordisk delay publication or presentation to allow the applicable RCA PM Party (or after the Closing Date, PlatformCo) to seek patent protection for patentable subject matter disclosed therein. In the event of any such request, Novo Nordisk agrees not to submit such publication or to make such presentation that contains patentable subject matter for an additional period of [***] in order to provide the applicable RCA PM Party (or after the Closing Date, PlatformCo) time to seek patent protection for any such material in such publication or presentation that the RCA PM Party (or after the Closing Date, PlatformCo) believes is patentable, and Novo Nordisk shall remove from such proposed publication any Confidential Information of the applicable RCA PM Party (or after the Closing Date, PlatformCo) as requested by such RCA PM Party (or after the Closing Date, PlatformCo). It is understood that the requirements of this Section 11.3.1 are subject to the publication rights of Third Party investigators and collaborators under the agreements pursuant to which any results of a Clinical Trial of a Licensed Product to be published have been or may be generated; *provided* that [***]. Notwithstanding the foregoing, neither the RCA PM Parties nor any of their Affiliates (or after the Closing Date, PlatformCo or any or its Affiliates) shall have the right to publish, publicly present, or otherwise publicly disclose information or data [***] the IND-Enabling Candidate or a Licensed Product (including the Program Epigenomic Controller therein), unless Novo Nordisk consents to such publication, public presentation or other public disclosure in its sole discretion.

11.3.2 **Compliance with Pharmaceutical industry accepted guidelines**. All publications made by Novo Nordisk relating to any Development Candidate or Licensed Product shall be prepared, presented, and published in accordance with the then-current version of the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals of the International Committee of Medical Journal Editors (ICMJE), or other pharmaceutical industry accepted guidelines mutually agreed upon by the Parties.

11.4 **Injunctive Relief**. Each Party acknowledges and agrees that breach of any of the terms of this Article 11 would cause irreparable harm and damage to the other Parties, that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Parties would be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of such terms by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages.

11.5 **Residual Information**. Notwithstanding anything to the contrary in this Agreement, this Article 11 shall not be construed to prohibit a Party's use of Residual Information for any purpose, including for Development and Commercialization of any products and services; *provided* that this Section 11.5 will not be deemed to excuse from the prohibitions of Article 11 [***]. "**Residual Information**" means the Confidential Information disclosed under this Agreement that consists of generalized knowledge, techniques, experiences, or Know-How gained or learned in the course of the activities under this Agreement and that is mentally retained in the unaided memories of the receiving Party's and its Affiliates' employees and other representatives without making reference to any document or other tangible media containing such Confidential Information.

12. INDEMNITY; LIMITATION OF LIABILITY; INSURANCE.

12.1 **Indemnification of PlatformCo by PM SpinCo and Shareholder**. PM SpinCo and Shareholder shall, jointly and severally, defend, indemnify and hold harmless PlatformCo and its Affiliates, and its and their respective officers, directors, employees, and agents (the "**PlatformCo Indemnitees**") from, against and in respect of any and all Third Party Losses incurred or suffered by any PlatformCo Indemnitee to the extent resulting from: (a) any breach by PM SpinCo, Pioneering Medicines, PMCo or Shareholder of this Agreement, which breach occurred prior to the Closing Date or (b) the negligence or intentional misconduct of the PM SpinCo Indemnitees in performing PM SpinCo's obligations or exercising PM SpinCo's rights under this Agreement, which negligence or intentional misconduct occurred prior to the Closing Date; *provided*, *however*, that PM SpinCo's obligations pursuant to this Section 12.1 shall not apply to the extent such Third Party Losses result from any act or omission (a) for which PlatformCo has an obligation to indemnify PM SpinCo pursuant to Section 12.2 or (b) occurring after the Closing Date. For the avoidance of doubt, following the Closing Date, neither Novo Nordisk nor PM SpinCo shall have any obligation to indemnify the PlatformCo Indemnitees under this Section 12.1 for any acts or omissions of PM SpinCo occurring prior to the Closing Date; *provided, however,* that nothing herein shall impact Shareholder's obligation to indemnify the PlatformCo Indemnitees under this Section 12.1 for any acts or omission of PM SpinCo, Pioneering Medicines, PMCo or Shareholder occurring prior to the Closing Date.

12.2 **Indemnification of PM SpinCo by PlatformCo**. PlatformCo shall defend, indemnify and hold harmless PM SpinCo and its Subsidiaries, Pioneering Medicines, PMCo and

its Subsidiaries, Shareholder and its Subsidiaries, and its and their respective officers, directors, employees, and agents (the "**PM SpinCo Indemnitees**") from, against and in respect of any and all Third Party Losses incurred or suffered by any PM SpinCo Indemnitee to the extent resulting from: (a) any breach by PlatformCo of this Agreement; or (b) the negligence or intentional misconduct of the PlatformCo Indemnitees in performing PlatformCo's obligations or exercising PlatformCo's rights under this Agreement; *provided*, *however*, that PlatformCo's obligations pursuant to this Section 12.2 shall not apply to the extent such Third Party Losses result from any act or omission for which PM SpinCo has an obligation to indemnify PlatformCo pursuant to Section 12.1.

12.3 **Indemnification of Novo Nordisk by PlatformCo**. PlatformCo shall defend, indemnify and hold harmless Novo Nordisk and its Affiliates (including, after the Closing Date, PM SpinCo), and its and their respective officers, directors, employees, and agents (the "**Novo Nordisk Indemnitees**") from, against and in respect of any and all Third Party Losses incurred or suffered by any Novo Nordisk Indemnitee to the extent resulting from: (a) any breach of this Agreement by PlatformCo; or (b) the negligence or intentional misconduct of any PlatformCo Indemnitee in performing PlatformCo's obligations or exercising PlatformCo rights under this Agreement; or (c) the Exploitation by or on behalf of PlatformCo or any of its Affiliates, or any of its or their respective officers, directors, employees, agents, licensees, sublicensees, contractors, subcontractors or consultants, of any Epigenomic Controller-LNP Candidate outside of the Field; *provided*, *however*, that PlatformCo's obligations pursuant to this Section 12.3 shall not apply to the extent such Third Party Losses result from any act or omission for which Novo Nordisk has an obligation to indemnify PlatformCo pursuant to Section 12.6.2.

12.4 **Indemnification of Novo Nordisk by PM SpinCo and Shareholder**. PM SpinCo and Shareholder shall, jointly and severally, defend, indemnify and hold harmless the Novo Nordisk Indemnitees from, against and in respect of any and all Third Party Losses incurred or suffered by any Novo Nordisk Indemnitee to the extent resulting from: (a) any breach of this Agreement by PM SpinCo, Pioneering Medicines, PMCo or Shareholder, which breach occurred prior to the Closing Date, (b) the negligence or intentional misconduct of any PM SpinCo Indemnitee in performing PM SpinCo's obligations or exercising PM SpinCo's rights under this Agreement, which negligence or intentional misconduct occurred prior to the Closing Date; or (c) the Exploitation by or on behalf of (i) any PM Entity or (ii) any Affiliate of any PM Entity, in each case ((i) and (ii)) other than PlatformCo and its Subsidiaries, or (iii) any officers, directors, employees, agents, licensees, sublicensees, contractors, subcontractors or consultants of the Persons described in clauses (i) and (ii), of any Epigenomic Controller-LNP Candidate outside of the Field; *provided*, *however*, that PM SpinCo's obligations pursuant to this Section 12.4 shall not apply to the extent such Third Party Losses result from (A) any act or omission for which Novo Nordisk has an obligation to indemnify PM SpinCo pursuant to Section 12.6.1 or (B) events occurring after the Closing Date.

12.5 **Joint Indemnification of Novo Nordisk**. (a) PlatformCo, on the one hand, and (b) PM SpinCo and Shareholder, jointly and severally, on the other hand, shall each ((a) and (b)) defend, indemnify and hold harmless the Novo Nordisk Indemnitees from, against and in respect of fifty percent (50%) of any and all Third Party Losses (totaling one hundred percent (100%) of such Third Party Losses between (a) and (b) collectively) incurred or suffered by any Novo Nordisk Indemnitee to the extent resulting from (i) an allegation by a Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, that the Exploitation by Novo Nordisk of the IND-Enabling Candidate or Licensed Product as contemplated by this Agreement infringes or misappropriates any Affiliate Core IP that is Controlled by such Flagship Affiliate, PMCo or any of its Subsidiaries, or Shareholder or any of its Subsidiaries, if PlatformCo has not obtained an in-license to such Affiliate Core IP as contemplated by Section 10.10.2(b)(i) or (ii) an allegation by a Third Party that the Exploitation by Novo Nordisk of the IND-Enabling Candidate or Licensed Product as contemplated by this Agreement infringes or misappropriates any Known Third Party Core IP that is Controlled by such Third Party if PlatformCo has not obtained an in-license to such Known Third Party Core IP as contemplated by Section 10.10.2(b)(i).

12.6 **Indemnification of RCA PM Parties by Novo Nordisk**.

12.6.1 **PM SpinCo**. Novo Nordisk shall defend, indemnify and hold harmless PM SpinCo and its Subsidiaries, Shareholder and its Subsidiaries, and their respective officers, directors, employees, and agents from, against and in respect of any and all Third Party Losses incurred or suffered by PM SpinCo or its Subsidiaries, Shareholder or its Subsidiaries, or their respective officers, directors, employees, and agents to the extent resulting from: (a) any breach by Novo Nordisk of this Agreement, which breach occurred prior to the Closing Date; (b) the negligence or intentional misconduct of Novo Nordisk Indemnitees in performing Novo Nordisk's obligations or exercising Novo Nordisk's rights under this Agreement, which negligence or intentional misconduct occurred prior to the Closing Date; or (c) the Exploitation by Novo Nordisk or any of its Affiliates, Sublicensees, contractors, subcontractors, agents or consultants (other than the RCA PM Parties under this Agreement) of any IND-Enabling Candidate or Licensed Product under or in connection with this Agreement; *provided*, *however*, that Novo Nordisk's obligations pursuant to this Section 12.6.1 shall not apply to the extent such Third Party Losses result from any act or omission for which PM SpinCo and Shareholder have an obligation to indemnify Novo Nordisk pursuant to Section 12.4 or 12.5. For the avoidance of doubt, Novo Nordisk shall have no obligation to indemnify any Person under this Section 12.6.1 for any acts or omissions of PM SpinCo occurring prior to the Closing Date.

12.6.2 **PlatformCo**. Novo Nordisk shall defend, indemnify and hold harmless the PlatformCo Indemnitees from, against and in respect of any and all Third Party Losses incurred or suffered by any PlatformCo Indemnitee to the extent resulting from: (a) any breach by Novo Nordisk of this Agreement; (b) the negligence or intentional misconduct of Novo Nordisk Indemnitees in performing Novo Nordisk's obligations or exercising Novo Nordisk's rights under

this Agreement; or (c) the Exploitation by Novo Nordisk or any of its Affiliates (other than Exploitation by PM SpinCo prior to the Closing Date), Sublicensees, contractors, subcontractors, agents or consultants (other than the RCA PM Parties under this Agreement) of any IND-Enabling Candidate or Licensed Product under this Agreement; *provided*, *however*, that Novo Nordisk's obligations pursuant to this Section 12.6.2 shall not apply to the extent such Third Party Losses result from any act or omission for which PlatformCo has an obligation to indemnify Novo Nordisk pursuant to Section 12.3 or 12.5. For the avoidance of doubt, Novo Nordisk shall have no obligation to indemnify the PlatformCo Indemnitees under this Section 12.6.2 for any acts or omissions of PM SpinCo occurring prior to the Closing Date.

12.7 **Notice of Claims**. Any Party seeking indemnification hereunder (the "**Indemnified Party**") shall give to the Party obligated to provide indemnification to such Indemnified Party (each, an "**Indemnifying Party**") a notice (a "**Claim Notice**") describing in reasonable detail and in good faith the facts giving rise to any Action by a Third Party for which indemnification may be sought (a "**Third Party Claim**"); *provided*, that a Claim Notice in respect of a Third Party Claim shall be given promptly after the action or suit is commenced; *provided further* that failure to give such notice shall not relieve the Indemnifying Party of its obligations hereunder, except and only to the extent the failure to give such notice actually and materially prejudices the Indemnifying Party with respect to such Third Party Claim.

12.8 **Defense**. Within [***] after delivery of a Claim Notice in accordance with Section 12.7, the Indemnifying Party shall assume sole control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party, *provided* that the Indemnified Party may participate therein at its own expense with counsel of its choosing. If the Indemnifying Party does not assume control of such defense, the Indemnified Party may control such defense (with counsel reasonably selected by the Indemnified Party and reasonably acceptable to the Indemnifying Party). Notwithstanding anything to the contrary in this Section 12.8, Novo Nordisk, as the Indemnified Party, may assume sole control of the defense of such Third Party Claim if Novo Nordisk reasonably believes that the Indemnifying Party does not have sufficient capital and other resources to adequately defend the Third Party Claim.

12.9 **Cooperation**. The Indemnifying Party shall keep the Indemnified Party advised of the status and material developments of such Third Party Claim and the defense thereof and shall reasonably consider recommendations made by the Indemnified Party with respect thereto. The Indemnified Party shall reasonably cooperate with the Indemnifying Party in defense of the Third Party Claim as reasonably requested by the Indemnifying Party, with all out-of-pocket costs of such cooperation to be borne by the Indemnifying Party.

12.10 **Settlement**. The Indemnified Party shall not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party shall not agree to any compromise or settlement of such Third Party Claim or consent to any judgment in respect thereof

that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party (other than a monetary obligation on the Indemnifying Party) without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed (unless such compromise or settlement involves (a) any admission of legal wrongdoing by the Indemnified Party, (b) any payment by the Indemnified Party that is not indemnified under this Agreement, or (c) the imposition of any equitable relief against the Indemnified Party (in which case, (a) through (c), the Indemnified Party may withhold its consent to such settlement in its sole discretion)).

12.11 **No Duplication of Recovery**. Without derogation from any of the terms and provisions hereof, the indemnification provisions of this Article 12 and those set forth in Article VIII of the Share Purchase Agreement are cumulative with respect to Novo Nordisk, PM SpinCo and the Shareholder, *provided* that any Indemnified Party shall be entitled to seek indemnification under this Agreement or the Share Purchase Agreement with respect to damages arising or resulting out of or relating to the same set of facts only up to the aggregate amount of such damages, subject to the limitations on indemnification and liability herein or therein. For the avoidance of doubt, with respect to PlatformCo's obligations under this Article 12, the indemnification provisions of this Article 12 are not cumulative with respect to any indemnification obligations of any of the other Parties, including under the Share Purchase Agreement and Option Agreement.

12.12 **No Consequential or Punitive Damages**.

12.12.1 **LIMITATION OF LIABILITY**. EXCEPT AS SET FORTH IN SECTION 12.12.2, NO PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, INCLUDING ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

12.12.2 **EXCLUSIONS**. THE LIMITATIONS AND DISCLAIMER SET FORTH IN SECTION 12.12.1 SHALL NOT APPLY TO: (A) A CLAIM ARISING FROM FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR BREACH OF ARTICLE 11; (B) A PARTY'S BREACH OF ARTICLE 6; OR (C) INDEMNIFIABLE LOSSES PURSUANT TO SECTIONS 12.1, 12.2, 12.3, 12.4, 12.5 OR 12.6.

12.13 **Insurance**. Each Party shall maintain, at its cost, insurance or self-insurance with respect to liabilities and other risks associated with its activities and obligations under this Agreement, including its indemnification obligations herein, in such amounts and on such terms

as are customary for prudent practices for companies in the biotechnology/pharmaceutical industry for the activities to be conducted by the Parties under this Agreement. Each Party shall furnish the other Parties with evidence of such insurance or self-insurance, upon reasonable request.

12.14 **Indemnification under the Whitehead Licenses**.

12.14.1 Novo Nordisk shall indemnify, defend, and hold harmless the Whitehead and its trustees, officers, faculty, students, medical and professional staff, employees, and agents and its respective successors, heirs and assigns (each, a "**Whitehead Indemnitee**") against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses) incurred by or imposed upon the Whitehead Indemnitees or any one of them, in connection with any Third Party claims, suits, investigations, actions, demands or judgments (a) arising out of the design, production, manufacture, sale, use in commerce, lease, or promotion by Novo Nordisk or its Affiliates or Sublicensees of any Licensed Product developed pursuant to this Agreement, [***], (c) [***] or (d) any breach of the Whitehead Licenses by Novo Nordisk or any of its Affiliates or Sublicensees.

12.14.2 Notwithstanding the foregoing, Novo Nordisk's indemnification obligations under this Section 12.14 does not apply to any liability, damage, loss or expense to the extent (a) that it is attributable to the grossly negligent activities of the Whitehead Indemnitees, or the intentional wrongdoing or intentional misconduct of the Whitehead Indemnitees or (b) result from any act or omission for which any PM Entity has an obligation to indemnify Novo Nordisk pursuant to Section 12.3, 12.4 or 12.5.

12.14.3 With respect to any claim for which indemnification is sought by a Whitehead Indemnitee pursuant to the terms of the Whitehead Licenses as incorporated herein, Novo Nordisk acknowledges and agrees that the provisions of the Whitehead Licenses relating to the procedures for indemnification shall apply as if such procedures were written in full herein, with the defined terms "Company" being deemed to refer to Novo Nordisk.

12.14.4 [***].

13. TERM AND TERMINATION.

13.1 **Term**. This Agreement shall become effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article 13, shall continue in full force and effect on a country-by-country and Licensed Product-by-Licensed Product basis, until the expiration of the last to expire Royalty Term in the Territory for such Licensed Product (the "**Term**"). Upon the expiration of the Royalty Term for a given Licensed Product in a given country in the Territory, the licenses granted to Novo Nordisk pursuant to Section 5.2 under the PlatformCo Licensed IP shall survive and become perpetual, irrevocable, fully paid-up and royalty free with respect to such Licensed Product in such country.

13.2 **Early Termination**.

13.2.1 **Termination upon Expiration or Termination of Option Agreement.** This Agreement shall automatically terminate in the event that (a) the Option Agreement expires pursuant to Section 6.2(a)(ii) thereof without the Option having been exercised by Novo Nordisk, (b) Novo Nordisk delivers a Rejection Notice and the Option Agreement and Share Purchase Agreement, if applicable, thereafter terminate or expire pursuant to the terms thereof or (c) the Share Purchase Agreement terminates in accordance with Section 10.1 of the Share Purchase Agreement; provided that, this Agreement shall not terminate in the event that Novo Nordisk elects its remedy under Section 10.3 of the Share Purchase Agreement (including pursuant to Section 2.2(b)(ii) of the Option Agreement).

13.2.2 **Termination by Novo Nordisk for Convenience**.

(a) **Prior to the Closing Date.** Prior to the Closing Date, Novo Nordisk shall have the right to terminate this Agreement in its entirety for convenience upon [***] prior written notice to the RCA PM Parties.

(b) **After the Closing Date.** From and after the Closing Date, Novo Nordisk shall have the right to terminate this Agreement in its entirety for convenience upon [***] prior written notice to PlatformCo.

13.2.3 **Termination for Material Breach**.

(a) **PM Entity Material Breach**.

(i) Upon any material breach of this Agreement by a PM Entity (such PM Entity, the "**Breaching PM Party**"), Novo Nordisk shall have the right, but not the obligation, to terminate this Agreement in its entirety (with respect to all PM Entities) by providing [***] written notice to the RCA PM Parties with respect to any material breach, which notice shall, in each case (a) expressly reference this Section 13.2.3, (b) reasonably describe the alleged breach which is the basis of such termination, and (c) clearly state Novo Nordisk's intent to terminate this Agreement if the alleged breach is not cured within the [***] cure period. Subject to Section 13.2.3(c), termination shall become effective at the end of the cure period unless the Breaching PM Party cures such breach during such cure period.

(ii) If Novo Nordisk has the right to terminate this Agreement pursuant to this Section 13.2.3 (*i.e.*, a final, binding determination pursuant to Article 14 that the Breaching PM Party was in material breach and failed to cure such material breach during the applicable cure period), Novo Nordisk may elect to keep this Agreement in effect. In such event, Novo Nordisk shall have the right, but not the obligation, to elect the remedies set forth in this Section 13.2.3(a)(ii) by written notice to the RCA PM Parties (or after the Closing Date,

PlatformCo), as applicable; *provided, however*, that Novo Nordisk may elect such remedies only once with respect to PlatformCo (i.e., either under (A) or (B) below) and only once with respect to the PM Entities other than PlatformCo, collectively (i.e., either under (A) or (C) below):

(A) [***]

(B) [***]

(C) [***]

For the avoidance of doubt, (x) Novo Nordisk shall have the right, in its sole discretion, to elect or forbear its remedies under Section 13.2.3(a)(ii)(A) – (C) if and when applicable, and any such forbearance by Novo Nordisk shall not prejudice Novo Nordisk's ability to elect such remedies, if and when applicable, with respect to any subsequent material breach of this Agreement by any PM Entity and (y) following exercise by Novo Nordisk of its remedies under Section 13.2.3(a)(ii)(A) – (C) with respect to a material breach by PlatformCo or the PM Entities other than PlatformCo, as applicable, nothing herein shall limit Novo Nordisk's ability to seek any remedy against such Person, at law or in equity, with respect to any subsequent material breach of this Agreement by such Person.

(b) **Novo Nordisk Material Breach.** Upon any material breach of this Agreement by Novo Nordisk, PlatformCo (acting for and on behalf of itself and PM SpinCo before the Closing Date) shall have the right, but not the obligation, to terminate this Agreement in its entirety by providing [***] written notice to Novo Nordisk with respect to any breach of any payment obligation under this Agreement and [***] written notice to the Novo Nordisk with respect to any other material breach, which notice shall, in each case (a) expressly reference this Section 13.2.3, (b) reasonably describe the alleged breach which is the basis of such termination, and (c) clearly state the RCA PM Parties' (PlatformCo's following the Closing Date) intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. Subject to Section 13.2.3(c), the termination shall become effective at the end of the applicable cure period unless Novo Nordisk cures such breach during such cure period, *provided* that, if the material breach is curable but is not capable of cure within such [***] period, then the cure period will be extended for so long as Novo Nordisk is diligently implementing a cure plan reasonably designed to cure such breach, *provided* further that, such cure period does not exceed [***] in total.

(c) **Disputes**. If the Party accused of materially breaching this Agreement (the "**Breaching Party**") notifies the other Party(ies) in writing that it disputes that it is in material breach or contends that it cured such material breach within the applicable cure period and, in either such case, promptly initiates the dispute resolution procedure set forth in Article 14, then termination under this Section 13.2.3 shall not become effective unless and until a final, binding determination pursuant to Article 14 that the Breaching Party was in material breach and failed to cure such material breach during the applicable cure period, *provided* that, if

the material breach concerned a payment hereunder and the Breaching Party remits such payment in full within [***] after such final determination, then the other Party(ies) shall not have a right to terminate this Agreement.

13.2.4 **Termination for Bankruptcy**. This Agreement may be terminated immediately, to the extent permitted by Applicable Laws, by (a) Novo Nordisk in the event of a Bankruptcy Event of either RCA PM Party or (b) PlatformCo (acting for and on behalf of itself and PM SpinCo before the Closing Date) in the event of a Bankruptcy Event of Novo Nordisk. As used herein, a "**Bankruptcy Event**" means the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings or the assignment of a substantial portion of the assets for the benefit of creditors; *provided*, *however*, that in the case of any involuntary bankruptcy, reorganization, liquidation or receivership proceeding the right to terminate this Agreement under this Section 13.2.4 shall only become effective if the Party subject to such proceeding consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] after the filing thereof.

13.2.5 **Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by PM SpinCo, PlatformCo, or Novo Nordisk are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

13.2.6 **Patent Challenge**.

(a) Except to the extent that this Section 13.2.6(a) is unenforceable under Applicable Laws of the applicable jurisdiction where the applicable PM SpinCo Licensed Patents are pending or issued, prior to the Closing Date, PM SpinCo has the right to [***], upon written notice to Novo Nordisk in the event that Novo Nordisk or any of its Affiliates or its or their Sublicensees (each, a "**Patent Challenging Party**") directly or indirectly brings a Patent Challenge with respect to any PM SpinCo Licensed Patent; *provided* that (i) this Section 13.2.6(a) shall not apply to any Patent Challenge that is (A) first made by a Patent Challenging Party in

defense of a claim of patent infringement under the applicable PM SpinCo Licensed Patents, or (B) made in ordinary course Patent Prosecution or Maintenance activities to distinguish the inventions claimed in any Patent Controlled by Novo Nordisk or its Affiliate from those claimed or disclosed in any PM SpinCo Licensed Patent or to respond to citation of the PM SpinCo Licensed Patent by a patent office in a rejection against any Patent Controlled by Novo Nordisk or its Affiliate (ii) PM SpinCo shall not have the right to terminate this Agreement under this Section 13.2.6(a) if Novo Nordisk (A) causes the Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws or causes its Affiliate or Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (B) in the case of a Patent Challenge brought by a Sublicensee, terminates such Sublicensee's sublicense to the PM SpinCo Licensed Patents being challenged by the Sublicensee, in each case ((A) and (B)), within [***] of PM SpinCo's notice to Novo Nordisk under this Section 13.2.6(a), (iii) this Section 13.2.6(a) shall not apply to any Patent Challenge that is due to the Patent Challenging Party responding to a court request, subpoena, or order, or an administrative agency request or order, or the applicable proceeding is initiated by a Patent office and not at the instigation of the Patent Challenging Party, and (iv) this Section 13.2.6(a) shall not apply to any Patent Challenge that was initiated by a Third Party that subsequently becomes an Affiliate of Novo Nordisk if (A) such Patent Challenge was initiated one (1) Calendar Year or more before the closing of the transaction whereby such Third Party became an Affiliate of Novo Nordisk, or (B) if such Patent Challenge was initiated within any such one (1) Calendar Year period, if Novo Nordisk causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws causes such Third Party to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge). This Section 13.2.6(a) shall have no further force or effect from and after the Closing Date.

(b) Except to the extent that this Section 13.2.6(b) is unenforceable under Applicable Laws of the applicable jurisdiction where the applicable PlatformCo Licensed Patents are pending or issued, PlatformCo has the right to [***] upon written notice to Novo Nordisk in the event that a Patent Challenging Party (including, after the Closing Date, PM SpinCo) directly or indirectly brings a Patent Challenge with respect to any PlatformCo Licensed Patent; *provided* that (i) this Section 13.2.6(b) shall not apply to any Patent Challenge that is (A) first made by a Patent Challenging Party (including, after the Closing Date, PM SpinCo) in defense of (1) a claim of patent infringement under the applicable PlatformCo Licensed Patents or (2) a claim of patent infringement under any New PlatformCo Patents to which Novo Nordisk does not elect to take a license pursuant to Section 10.12 or (B) made in ordinary course Patent Prosecution or Maintenance activities to distinguish the inventions claimed in any Patent Controlled by Novo Nordisk or its Affiliate from those claimed or disclosed in any PlatformCo Licensed Patent or to

respond to citation of the PlatformCo Licensed Patent by a patent office in a rejection against any Patent Controlled by Novo Nordisk or its Affiliate, (ii) PlatformCo shall not have the right to terminate this Agreement under this Section 13.2.6(b) if Novo Nordisk (A) causes the Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws or causes its Affiliate (including, after the Closing Date, PM SpinCo) or Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (B) in the case of a Patent Challenge brought by a Sublicensee, terminates such Sublicensee's sublicense to the PlatformCo Licensed Patents being challenged by the Sublicensee, in each case ((A) and (B)), within [***] PlatformCo's notice to Novo Nordisk under this Section 13.2.6(b), (iii) this Section 13.2.6(b) shall not apply to any Patent Challenge that is due to the Patent Challenging Party responding to a court request, subpoena, or order, or an administrative agency request or order, or the applicable proceeding is initiated by a Patent office and not at the instigation of the Patent Challenging Party, and (iv) this Section 13.2.6(b) shall not apply to any Patent Challenge that was initiated by a Third Party that subsequently becomes an Affiliate of Novo Nordisk if (A) such Patent Challenge was initiated one (1) Calendar Year or more before the closing of the transaction whereby such Third Party became an Affiliate of Novo Nordisk, or (B) if such Patent Challenge was initiated within any such one (1) Calendar Year period, if Novo Nordisk causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws or causes such Third Party to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge).

13.3 **Effects of Termination**.

13.3.1 **Effects of Termination Generally**. If this Agreement is terminated by a Party in accordance with this Article 13 at any time and for any reason, in addition to the other rights and remedies that may be available to the Parties under this Agreement, the following terms shall apply, which terms shall not be construed to limit any such rights or remedies:

(a) **Licenses**. Other than the licenses granted to an RCA PM Party under Section 10.3.1, to Novo Nordisk under Section 10.3.5, and to the Parties under Section 10.3.3(a), the Parties' rights, licenses, including any Sublicenses, and obligations under this Agreement shall terminate and neither Party shall have any further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this Section 13.3.

(b) **Return of Confidential Information**. Within [***] after the effective date of termination of this Agreement, each Party shall, and shall cause its Affiliates to (i) destroy all tangible items solely comprising, bearing or containing any Confidential Information of the other Parties that are in such Party's or its Affiliates' possession or control, and provide

written certification of such destruction, or (ii) prepare such tangible items of the other Parties' Confidential Information for shipment to the applicable other Party, as such other Party may direct, at such other Party's expense; *provided*, *however*, that, in any event, (A) each Party may retain copies of the Confidential Information of the other Parties to the extent necessary to perform its obligations or exercise its rights that survive termination of this Agreement; and (B) each Party may retain one (1) copy of the Confidential Information of the other Parties for its legal archives.

13.3.2 **Termination Without Acquisition Closing**. Without limiting Section 13.3.1, if this Agreement terminates pursuant to Section 13.2.1 then, notwithstanding anything to the contrary herein, neither PM SpinCo, PlatformCo nor any of their respective Affiliates or designees shall practice or otherwise Exploit the RCA PM Parties Joint Developed IP or PM and NN Joint Developed IP without the prior written consent of the other such Party (i.e., PlatformCo or PM SpinCo). For clarity, this Agreement shall not terminate in the event that Novo Nordisk elects its remedy under Section 10.3 of the Share Purchase Agreement (including pursuant to Section 2.2(b)(ii) of the Option Agreement).

13.3.3 **Termination by PlatformCo for Cause or by Novo Nordisk for Convenience**. If this Agreement is terminated by PlatformCo pursuant to Sections 13.2.3(b), 13.2.4 or 13.2.6 or by Novo Nordisk pursuant to Section 13.2.2, then, in addition to the provisions of Section 13.3.1, the following terms shall apply:

(a) **Transitioning Activities**. If there are any on-going Clinical Trials of Licensed Products as of the effective date of termination of this Agreement, PlatformCo and Novo Nordisk shall negotiate in good faith to establish an appropriate course of action, which may include transitioning activities from Novo Nordisk to PlatformCo or its designee, with due regard for patient safety and the rights of any subjects that are participants in any clinical studies of Licensed Products, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all Applicable Laws.

(b) **Regulatory**. Novo Nordisk shall and hereby does, and shall cause its Affiliates to, (i) effective as of the effective date of termination, assign to PlatformCo all of its rights, title, and interests in and to all [***] to the extent allowed under Applicable Laws that are then Controlled by Novo Nordisk or any of its Affiliates and that [***] (each, a "**Grantback Product**") and (ii) to the extent assignment pursuant to clause (i) is delayed or is not permitted by the applicable Regulatory Authority, Novo Nordisk shall and hereby does grant to PlatformCo an exclusive right of reference to such items so affected, to the extent allowed under Applicable Laws, in each case for the continued Development and Commercialization thereof by PlatformCo and its Affiliates and sublicensees of Grantback Products in accordance with Section 13.3.3(d).

(c) **Assignment of RCA PM Parties Joint Developed IP**. Without limiting Section 13.2.3(b), Novo Nordisk shall and hereby does, and shall cause its Affiliates' to, effective as of the effective date of termination, assign to PMCo or its designee all of its and their

right, title and interest in and to the RCA PM Parties Joint Developed IP. Notwithstanding anything to the contrary herein, neither PMCo, PlatformCo nor any of their respective Affiliates or designees shall practice or otherwise Exploit the RCA PM Parties Joint Developed IP or PM and NN Joint Developed IP without the prior written consent of other such party.

(d) **License**. Subject to the remainder of this Section 13.3.3(d), Novo Nordisk (for itself and its Affiliates) shall grant to PlatformCo an exclusive, worldwide, royalty-bearing license, with the right to sublicense (through multiple tiers) (i) under [***] and (ii) if termination occurs after Regulatory Approval of a Grantback Product, to use any Trademarks that are specific to and solely used for such Grantback Product (which shall not include any Trademarks that contain the corporate or business name(s) of Novo Nordisk or any of its Affiliates or Sublicensees), in each case ((i) and (ii)) that are Controlled by Novo Nordisk or its Affiliates as of the effective date of termination and are [***] to Develop, Manufacture or Commercialize any Grantback Product (collectively (clauses (i) and (ii)), the "**Grantback IP**") [***] to Develop, Manufacture or Commercialize such Grantback Product in the Field in the Territory as such Grantback Product [***]. [***].

(e) **Inventory**. PlatformCo shall have the right to purchase all of Novo Nordisk's and its Affiliates' then-current remaining inventory of Grantback Products. If PlatformCo makes such purchase, Novo Nordisk shall provide the applicable primary drug substance reference standard record of analysis within its Control, and a summary report describing its characterization. No raw materials (including chromatography resins, filters, or consumables) shall be transferred to PlatformCo. PlatformCo shall have the right to purchase such remaining Grantback Product inventory at a price equal to Novo Nordisk's fully burdened Manufacturing cost, as reasonably determined by Novo Nordisk.

(f) **Transition Plan**. PlatformCo and Novo Nordisk shall negotiate in good faith regarding a plan acceptable to both Parties for the transition to PlatformCo of Development of the IND-Enabling Candidate and the Licensed Products and commercially reasonable financial terms therefor. Novo Nordisk shall, at PlatformCo's cost and expense, provide other assistance or take any other actions, in each case reasonably requested by PlatformCo, as necessary to transfer to PlatformCo the Development of the IND-Enabling Candidate and Licensed Products, and shall execute all documents as may be reasonably requested by PlatformCo in order to give effect to this Section 13.3.3(f) and to enable PlatformCo to assume the Development of the IND-Enabling Candidate and Licensed Products.

(g) **Patent Information**. Novo Nordisk, if requested in writing by PlatformCo or PMCo (or its designee), shall provide any material correspondence with the relevant Patent offices pertaining to Novo Nordisk's Prosecution and Maintenance of the PlatformCo Licensed Product-Specific Patents to the extent not previously provided to PlatformCo during the course of performance under this Agreement.

13.4 **Cooperation**. Each Party shall use reasonable efforts to cause its Affiliates, its and their sublicensees and subcontractors to comply with the obligations in Section 13.3.

13.5 **Accrued Obligations**. Expiration or termination of this Agreement for any reason shall not release a Party from any obligation or liability which, on the effective date of such expiration or termination, has already accrued to the other Parties or which is attributable to a period prior to such expiration or termination.

13.6 **Survival**. This Section 13.6, the provisions set forth in the following Articles and Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections necessary to give them effect, shall survive the expiration or termination of this Agreement: [***].

14. DISPUTE RESOLUTION.

14.1 **Generally**. Except as otherwise expressly provided herein (including as provided in Section 2.4 and Section 13.3.3(d)), disputes of any nature arising under, relating to, or in connection with this Agreement, including any questions regarding its formation, existence, validity, enforceability, performance, interpretation, breach or termination ("**Disputes**") shall be resolved pursuant to this Article 14.

14.2 **Dispute Escalation**. In the event of a Dispute among the Parties, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within [***] from receipt of a written notice of a Dispute, any Party may, by written notice to the other, have such Dispute referred to the Executive Officers (or their designees, which designee is required to have decision-making authority on behalf of such Party), who shall attempt in good faith to resolve such Dispute by negotiation and consultation for a [***] period following receipt of such written notice. Following such escalation, (a) for any Dispute of a type for which this Agreement specifies that [***] shall have final decision rights, [***] may make a final decision, and (b) for any other Dispute, such Dispute shall be resolved in accordance with Section 14.3.

14.3 **Arbitration**. Subject to Section 2.4 and Section 13.3.3(d), any Dispute (other than a type for which this Agreement specifies that [***] shall have final decision rights) that is not resolved under the process outlined in Section 14.2 shall be finally settled by arbitration under the Rules of Arbitration of the International Chamber of Commerce. The seat of arbitration shall be New York, New York. The language of the arbitration shall be English. The arbitral tribunal shall be composed of three (3) arbitrators, each of whom shall be impartial and independent. The RCA PM Parties (or after the Closing Date, PlatformCo) shall nominate one (1) arbitrator, Novo Nordisk shall nominate one (1) arbitrator, and the two arbitrators so nominated shall nominate the presiding arbitrator. The arbitrators shall not have the power to award any damages expressly prohibited by Section 12.12. The Parties shall equally share the costs of the arbitration including the

administrative fees and the fees payable to the arbitrators, but each Party shall bear its own costs of legal representation. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Applicable Laws, neither the RCA PM Parties (or after the Closing Date, PlatformCo) or Novo Nordisk nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both the RCA PM Parties (or after the Closing Date, PlatformCo) and Novo Nordisk (each such consent not to be unreasonably withheld, delayed or conditioned).

14.4 **Injunctive Relief**. Notwithstanding the dispute resolution procedures set forth in this Article 14, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, including without first submitting to any dispute resolution procedures hereunder if necessary to preserve the status quo pending the dispute resolution procedures hereunder.

14.5 **Interpretation; Final Decision**. Notwithstanding anything contained herein to the contrary, the interpretation and enforcement of the arbitration provisions contained herein shall be governed by the Federal Arbitration Act, 9 U.S.C. Section 1 et seq. The arbitration award(s) shall be final and binding on the Parties and their Affiliates and the Parties expressly exclude any and all rights to set aside or otherwise challenge any award by the arbitrators insofar as such exclusion can validly be made, except in the case of fraud, willful misconduct or manifest error. Judgment upon any award may be entered in any court having jurisdiction thereof and shall be entitled to recognition and enforcement under the United Nations Convention on the Recognition and Enforcement of Arbitral Awards (New York, 1958).

15. MISCELLANEOUS.

15.1 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the state of New York, without respect to its conflict of laws rules or principles that might otherwise refer construction or interpretation of this Agreement to the substantive laws of another jurisdiction; *provided*, *however*, that any dispute relating to the scope, validity, enforceability or infringement of any Patents shall be governed by, and construed and enforced in accordance with, the substantive laws of the jurisdiction in which such Patents apply. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

15.2 **Entire Agreement**. This Agreement and the attached Exhibits and the documents and instruments and other agreements specifically referred to herein, including the Option Agreement and the Share Purchase Agreement and the exhibits thereto, constitute the entire agreement among the Parties as to the subject matter of this Agreement and shall supersede and merge all prior and contemporaneous negotiations, representations, agreements and understandings among the Parties regarding the same (other than the Prior Agreement), including,

effective as of the Effective Date, [***] (*provided* that all information disclosed or exchanged under such [***] shall be treated as Confidential Information hereunder).

15.3 **Waivers and Modifications**. The failure of any Party to insist on the performance of any obligation, term, provision or condition hereunder shall not be deemed to be a waiver of such obligation, term, provision or condition. Waiver of any breach of any obligation, term, provision or condition hereunder shall not be deemed to be a waiver of any other breach of such obligation, term, provision or condition or any other provision on such occasion or any succeeding occasion. No waiver, modification, release, or amendment of any obligation, term, provision or condition of this Agreement shall be valid or effective unless in writing and signed by each of the Parties.

15.4 **Severability**. If any one or more of the provisions of this Agreement is held to be void, invalid or unenforceable by a court of competent jurisdiction in any situation in any jurisdiction, the provision shall be considered severed from this Agreement and shall not affect the validity or enforceability of the remaining provisions hereof or the validity or enforceability of the invalid, void or unenforceable provision in any other situation or in any other jurisdiction. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.5 **Assignment**.

15.5.1 **In General**. This Agreement may not be assigned by Novo Nordisk or an RCA PM Party, nor may Novo Nordisk or an RCA PM Party delegate its obligations or otherwise transfer any rights created by this Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other such Parties, which consent shall not be unreasonably withheld, delayed or conditioned; *provided* that Novo Nordisk or PlatformCo may assign this Agreement (a) to an Affiliate and (b) to such Party's successor in connection with the merger, consolidation, sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement. In the event Novo Nordisk assigns this Agreement to a permitted assign in accordance with the terms and conditions set forth in this Section 15.5, [***]. This Agreement may not be assigned by Shareholder or PMCo, nor may Shareholder or PMCo delegate its obligations or otherwise transfer any rights created by this Agreement, except as expressly permitted hereunder, without the prior written consent of the other Parties. [***]. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein shall be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 15.5. Any assignment or attempted assignment by a Party in violation of the terms of this Section 15.5 shall be null and void.

15.5.2 **Revenue Assignment**. PlatformCo may monetize its right to receive Royalty Payments or Milestone Payments under this Agreement (together with corresponding rights under Article 8) by assigning to [***] (such Third Party, the "**Revenue Buyer**" and such assignment the "**Revenue Assignment**"), such right (or a portion thereof) subject to this Section 15.5.2. For clarity, PlatformCo may not assign its rights to receive Royalty Payments or Milestone Payments under this Agreement to [***] without the prior written consent of Novo Nordisk, which consent shall not be unreasonably withheld, conditioned or delayed.

(a) If at any time during the Term, PlatformCo desires to effect a Revenue Assignment, PlatformCo shall provide Novo Nordisk with written notice of such intention (the "**Revenue Buyout Notice**"). Novo Nordisk will have [***] from the receipt of such Revenue Buyout Notice (the "**Notice Period**") to review the opportunity and determine whether to seek to negotiate a buyout of its Royalty Payments obligations (or a portion thereof, as applicable) hereunder (a "**Revenue Buyout**"). If Novo Nordisk determines to seek to negotiate a Revenue Buyout, then PlatformCo and Novo Nordisk shall exclusively negotiate in good faith for a period of [***] (the "**Negotiation Period**") to reach agreement on Revenue Buyout terms. If Novo Nordisk does not exercise its Revenue Buyout right of first negotiation within the Notice Period or the Parties are unable to reach agreement with respect to a Revenue Buyout during the Negotiation Period, then in each such instance, [***]; *provided, however*, that, in the event such Revenue Assignment is executed, all of Novo Nordisk's reporting obligations under this Agreement shall terminate other than the obligation to provide royalty reports under Section 8.5.3 and as necessary to satisfy PlatformCo's reporting obligations to Whitehead pursuant to the Whitehead License (collectively, "**Required Whitehead Reports**"), which Required Whitehead Reports PlatformCo shall not share with the Revenue Buyer. A Revenue Assignment shall not affect Novo Nordisk's right to take any offsets or reductions in payments otherwise provided under this Agreement, the Option Agreement or the Share Purchase Agreement.

(b) PlatformCo shall not grant any lien or security interest in any PlatformCo Licensed IP in connection with the Revenue Assignment.

(c) Subject to compliance with this Section 15.5.2, assignment by PlatformCo of its right to receive Royalty Payments under this Agreement to a Revenue Buyer shall not be a violation of Section 15.5.1.

15.6 **Notices**. All notices, deliveries and other communications pursuant to this Agreement shall be in writing and in English and shall be deemed given if delivered personally, sent by email (and promptly confirmed by globally recognized express delivery service) or delivered by globally recognized express delivery service to the Parties at the email or addresses set forth below or to such other email or address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such notice, delivery or communication shall be deemed to have been delivered and received (a) in the case of personal delivery, on the delivery date, (b) in the case of email, on the delivery date (or if delivered on a

non-Business Day, then on the next Business Day), and (c) in the case of a globally recognized express delivery service, on the date of receipt.

If to Novo Nordisk:

Novo Nordisk A/S
Novo Allé
2880 Bagsvaerd
Denmark
Attention: Head of Early Innovation, Outreach & Alliances

with copies (which shall not constitute notice) to:

Novo Nordisk A/S
Novo Allé
2880 Bagsvaerd
Denmark
Attention: General Counsel, Legal Department

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attention: Steven D. Barrett
Email: steven.barrett@wilmerhale.com

If to PM SpinCo (prior to the Closing Date):

Pioneering Medicines 08, Inc.
c/o Flagship Pioneering
55 Cambridge Pkwy, Suite 800E
Cambridge, MA 02142
Attention: Paul Biondi
Email: [***]

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Christopher J. Denn; Nancy L. Urizar
Email: CDenn@goodwinlaw.com; NUrizar@goodwinlaw.com

If to PMCo:

PM (NN) Explorations, Inc.
c/o Flagship Pioneering
55 Cambridge Pkwy, Suite 800E
Cambridge, MA 02142
Attention: Paul Biondi
Email: [***]

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Christopher J. Denn; Nancy L. Urizar
Email: CDenn@goodwinlaw.com; NUrizar@goodwinlaw.com

If to Shareholder:

Pioneering Medicines (NN), LLC
c/o Flagship Pioneering
55 Cambridge Pkwy, Suite 800E
Cambridge, MA 02142
Attention: Paul Biondi
Email: [***]

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Christopher J. Denn; Nancy L. Urizar
Email: CDenn@goodwinlaw.com; NUrizar@goodwinlaw.com

If to PlatformCo:

Omega Therapeutics, Inc.
140 First Street, Suite 501
Cambridge, MA 02141
Attention: Mahesh Karande
Email: [***]

with a copy (which shall not constitute notice) to:

Omega Therapeutics, Inc.
140 First Street, Suite 501
Cambridge, MA 02141
Attention: Ling Zeng
Email: [***]

15.7 **Force Majeure**. [***] no Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, hurricanes, earthquakes, war, acts of war (whether war be declared or not), terrorism, civil unrest, embargoes, insurrections, riots, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), shortage, government actions, floods, epidemics, pandemics or quarantines; *provided*, *however*, that the affected Party promptly notifies the other Parties and further *provided* that the affected Party shall use Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

15.8 **Relationship of the Parties**. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship among the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided therein. There are no express or implied Third Party beneficiaries hereunder (except for Whitehead for purposes of Section 12.14 and Section 15.9).

15.9 **Compliance with Exports Controls Laws**. [***]

15.10 **Affiliates and Contractors**. To the extent that this Agreement imposes obligations on Affiliates or independent contractors of a Party, such Party shall cause its Affiliates and its independent contractors to perform such obligations, as applicable. Either Party may use one or more of its Affiliates or independent contractors to perform its obligations and duties or exercise its rights under this Agreement, solely to the extent permitted and as specified in this Agreement; *provided*, *however*, that (a) each such Affiliate or contractor shall perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement as if such Affiliate or contractor were a party hereto, (b) the performance of any obligations of a Party by its Affiliates or independent contractors shall not diminish, reduce or eliminate any obligation of such Party under this Agreement, except to the extent satisfied by such Affiliate or contractor and (c) subject to such Party's assignment to an Affiliate pursuant to Section 15.5, such Party shall remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement.

15.11 **Cumulative Remedies**. All rights and remedies of the Parties hereunder shall be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at law or otherwise.

15.12 **Interpretation**. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

15.12.1 The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The word "will" shall be construed to have the same meaning and effect as the word "shall," and vice versa. The word "any" means "any and all" unless otherwise clearly indicated by context. The words "including", "include" and "includes" shall be deemed to be followed by the phrase "without limitation." The word "or" is disjunctive but not necessarily exclusive.

15.12.2 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein or therein), (b) any reference to any Applicable Laws herein shall be construed as referring to such Applicable Laws as from time to time enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include such Person's successors and assigns, and (d) all references herein to Articles, Sections or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections and Exhibits of this Agreement.

15.12.3 Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

15.13 **Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument. PDF execution and delivery of this Agreement by any Party shall constitute a legal, valid and binding execution and delivery of this Agreement by such Party.

[*Signature Page Next*]

IN WITNESS WHEREOF, the Parties have caused this Research Collaboration Agreement to be executed by their respective duly authorized officers as of the Effective Date.

NOVO NORDISK A/S

By: /s/ Marcus Schindler
Name: Marcus Schindler
Title: Executive Vice President and Chief Scientific Officer

IN WITNESS WHEREOF, the Parties have caused this Research Collaboration Agreement to be executed by their respective duly authorized officers as of the Effective Date.

OMEGA THERAPEUTICS, INC.

By: /s/ Mahesh Karande
Name: Mahesh Karande
Title: President and Chief Executive Officer

IN WITNESS WHEREOF, the Parties have caused this Research Collaboration Agreement to be executed by their respective duly authorized officers as of the Effective Date.

PM (NN) EXPLORATIONS, INC.

By: /s/ Paul Biondi
Name: Paul Biondi
Title: President

PIONEERING MEDICINES (NN), LLC

By: /s/ Paul Biondi
Name: Paul Biondi
Title: President

PIONEERING MEDICINES 08, INC.

By: /s/ Paul Biondi
Name: Paul Biondi
Title: President

Schedule 1.19

Validation Criteria for Backup Target Validation Studies

[***]

Schedule 1.20

Contents of Backup Target Validation Studies Data Package

[***]

Schedule 1.65

Development Candidate Criteria & Development Candidate Data Package Contents

[***]

Schedule 1.114

In Vitro Proof of Concept Criteria

[***]

Schedule 1.118

IND-Enabling Data Package Contents & IND-Enabling Criteria

[***]

Schedule 1.127

Initial Backup Target Studies Data Package Content

[***]

136

MACROBUTTON DocID \\4126-6252-2948 v34

Schedule 1.139

Knowledge of PlatformCo

[***]

Schedule 1.217

PlatformCo Licensed Patents

[***]

MACROBUTTON DocID \\4126-6252-2948 v34

Schedule 1.222
PM Management

[***]

Schedule 1.229

PM SpinCo Licensed Patents

[***]

MACROBUTTON DocID \\4126-6252-2948 v34

Schedule 1.244

List of Proposed and Prioritized Backup Targets for Computational Assessment

[***]

MACROBUTTON DocID \\4126-6252-2948 v34

Schedule 1.312

Upstream Licenses

[***]

Schedule 2.4

Resolution of Disputed Criteria Achievement Matters

[***]

Schedule 3.1.1

Initial R&D Plan and Initial R&D Budget

[***]

144

MACROBUTTON DocID \\4126-6252-2948 v34

Schedule 3.7

Novo Nordisk Principles for the Use of Animals

[***]

MACROBUTTON DocID \\4126-6252-2948 v34

Schedule 4.1.3(b)

Form of Development Report

[***]

Schedule 5.5.5

Whitehead Milestones

[***]

147

MACROBUTTON DocID \\4126-6252-2948 v34

Schedule 8.1

Novo Nordisk's Invoicing Instructions

[***]

Schedule 10.3.5(d)

PlatformCo Background Patents (Other Than PlatformCo Licensed Patents)

[***]

Schedule 11.2.2

PlatformCo Press Release

[***]

Schedule 13.3.3(d)
Baseball Arbitration For [***]

[***]

151

MACROBUTTON DocID \\4126-6252-2948 v34

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-258365 on Form S-8 and 333-268254 on Form S-3 of our report dated March 28, 2024, 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, 2023.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 28, 2024

Exhibit 31.1

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 28, 2024

By: /s/ Mahesh Karande

Mahesh Karande
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Joshua Reed, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 28, 2024

By: /s/ Joshua Reed

Joshua Reed
Chief Financial Officer

Exhibit 32.1

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

In connection with the Annual Report of Omega Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023, 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 28, 2024

By: /s/ Mahesh Karande
Mahesh Karande
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the Annual Report of Omega Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joshua Reed, 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 28, 2024

By: /s/ Joshua Reed
Joshua Reed
Chief Financial Officer

Exhibit 97

OMEGA THERAPEUTICS, INC. POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

Omega Therapeutics, Inc. (the "***Company***") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of October 2, 2023 (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to current and former Officers of the Company.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its solediscretion, determine the manner ofrecovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensationmay be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board of Directors of the Company (the "***Board***") may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7. No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8. Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similarpolicies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "***Other Recovery Arrangements***"). The remedy specifiedin this Policy shall not be exclusive and shall be in additionto every other right or remedy at law or in equitythat may be availableto the Company or an affiliate of the Company.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

"***Committee***" means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Financial Reporting Measure***" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non-GAAP/IFRS financial measures, as well as stock or share price and total equityholder return.

"***GAAP***" means United States generally accepted accounting principles.

"***IFRS***" means international financial reporting standards as adopted by the International Accounting Standards Board.

"***Impracticable***" means (a) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company (i) has made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the issuer has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Officer***" means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Three-Year Period***" means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement.The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.