As confidentially submitted to the Securities and Exchange Commission on May 7, 2021

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Omega Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	2836	81-3247585
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

20 Acorn Park Drive
Cambridge, MA 02140
(617) 949-4360
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mahesh Karande
President and Chief Executive Officer
20 Acorn Park Drive
Cambridge, MA 02140
(617) 949-4360
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ _____

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ _____

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ _____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See 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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, $0.001 par value per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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Subject to Completion. Dated , 2021.

Shares

Omega Therapeutics, Inc.

Common Stock

This is an initial public offering of shares of common stock of Omega Therapeutics, Inc.

We are offering shares of our common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share will be between $ and $. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "OMGA."

We are an "emerging growth company" and a "smaller reporting company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves risks. See "Risk Factors" beginning on page 14 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to Omega Therapeutics, Inc.	$	$

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

To the extent that the underwriters sell more than shares of common stock, the underwriters have the option to purchase up to an additional shares from us at the initial price to public less the underwriting discount.

The underwriters expect to deliver the shares against payment in New York, New York on , 2021.

Goldman Sachs & Co. LLC **Jefferies** **Piper Sandler**

Wedbush PacGrow

Prospectus dated , 2021.

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Through and including , 2021 (25 days after the commencement of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

We have proprietary rights to trademarks, trade names and service marks appearing in this prospectus that are important to our business. Solely for convenience, the trademarks, trade names and service marks may appear in this prospectus without the ® and ™ symbols, but any such references are not intended to indicate, in any way, that we forgo or will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, trade names and service marks. All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled "Risk factors," "Special note regarding forward-looking statements" and "Management's discussion and analysis of financial condition and results of operations" and our financial statements and the related notes included elsewhere in this prospectus, before making any investment decision. Unless the context otherwise requires, the terms "Omega," "Omega Therapeutics," the "Company," "we," "us" and "our" relate to Omega Therapeutics, Inc.

Overview

At Omega Therapeutics, our goal is to pioneer a new class of DNA-sequence-targeting, mRNA-encoded therapeutics to fundamentally transform human medicine in the service of patients. Our pioneering OMEGA Epigenomic Programming platform is designed to coopt nature's universal operating system by harnessing the power of epigenetics, the mechanism for gene control and cell differentiation. We have deciphered the three-dimensional architecture of the human genome and its accompanying regulators, which are organized into distinct and evolutionarily conserved structures called Insulated Genomic Domains, or IGDs. IGDs are the fundamental structural and functional units of gene control and cell differentiation and act as the "control room" of biology. Most diseases are caused by aberrant gene expression rooted in alterations in IGDs. The OMEGA platform has enabled us to systematically identify and validate thousands of novel DNA-sequence-based epigenomic "zip codes" within IGDs. We call these epigenomic targets EpiZips. We rationally design and engineer modular, programmable mRNA-encoded epigenetic medicines, which we call Omega Epigenomic Controllers, or OECs, to target EpiZips for Precision Genomic Control. This enables us to precisely tune genes to a desired level of expression and to control the duration of expression. Through this approach, we believe that the OMEGA platform has broad potential applicability across a range of diseases and conditions. Our pipeline currently consists of programs that span regenerative medicine, multigenic diseases including immunology, oncology, and select monogenic diseases. We have achieved *in vivo* proof-of-concept of our OECs in multiple disease models for various indications, including hepatocellular carcinoma, or HCC, non-small cell lung cancer, or NSCLC, and acute respiratory distress syndrome, or ARDS. We expect to achieve *in vivo* preclinical proof-of-concept for multiple additional programs in . If successful, we plan to initiate investigational new drug application, or IND, enabling studies for multiple programs beginning in .

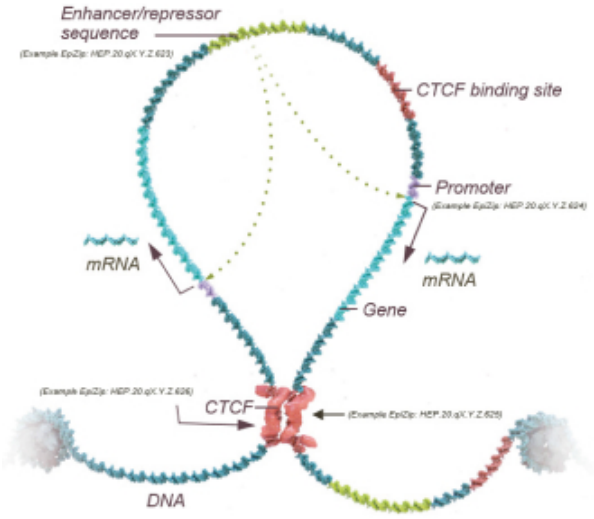
Scientific Underpinnings of the OMEGA Platform

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

Gene expression in cells is generally controlled by a highly diverse class of regulatory elements, such as enhancers, repressors and promoters. These regulatory elements are relatively short

segments of DNA that act as binding sites for protein transcription factors that in turn recruit other proteins to activate transcription of targeted genes. Current research indicates that genes and their associated regulatory elements reside in a modular fashion within IGDs. The chromosomal-looping structure of IGDs anchored by the CCCTC-binding factor, CTCF, at the base ensures that interactions between genes and their regulatory elements are insulated from neighboring IGDs and extraneous regulatory factors. 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. The OMEGA platform leverages the structure of IGDs as insulated "control units" encompassing genes and their regulatory elements with the goal of correcting this dysregulation and treating disease.

Graphical Representation of an IGD



OMEGA Epigenomic Programming Platform

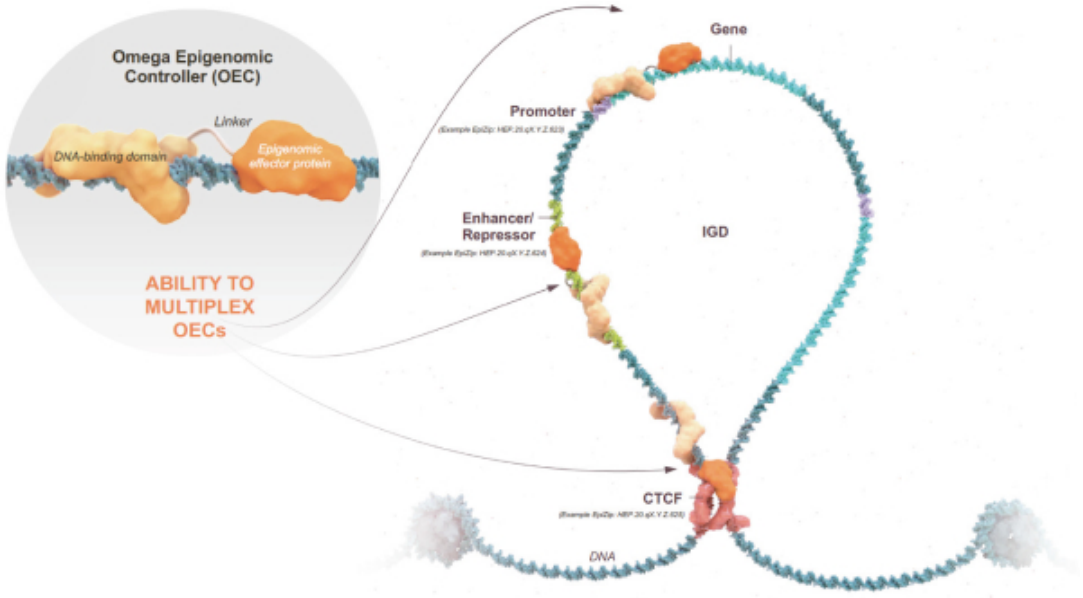
The OMEGA platform represents an unprecedented approach to developing therapeutics to treat the epigenetic basis of disease by precisely controlling gene expression without altering native DNA sequences. We believe that our mRNA-encoded OECs' ability to precisely target and provide tunable and durable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

The OMEGA platform consists of four pillars:

1. **Proprietary Database of IGDs and EpiZips.** Thousands of novel DNA-sequence-based epigenomic targets covering over 90% of human IGDs, identified through proprietary algorithms and machine-learning tools mining our own and public databases.

2. **Modular Programmable Epigenetic Medicines Encoded as mRNA (OECs).** Engineered and modular mRNA-encoded medicines with a DNA-binding protein to target a specific EpiZip and an effector protein to up- or down-regulate gene expression and control the duration of expression.

Omega Epigenomic Controller



3. **Engineered, Customized Drug Delivery.** Lipid-nanoparticle delivery technology validated in third-party clinical trials. Deep formulation expertise to engineer and customize technological improvements. Continued innovation in other emerging technologies.

4. **Industry-Leading Expertise.** Codified learnings and insights gleaned from lead programs to continue optimizing the platform and inform the discovery and development of subsequent product candidates. Continued additions to the knowledge bank of EpiZips and OECs.

Our Foundational Computational Capabilities

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

Advantages of the OMEGA Platform

We believe the OMEGA platform has the following advantages:

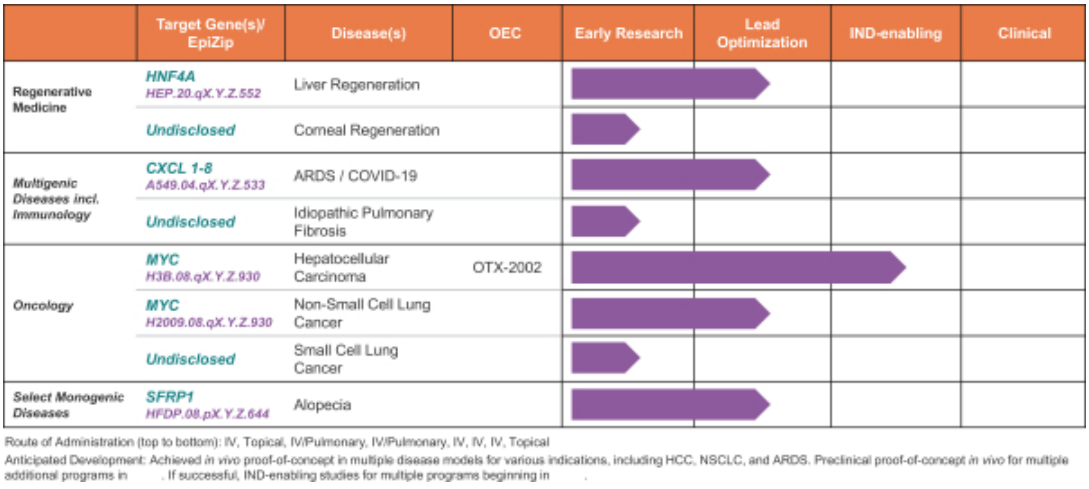
- Pioneering IGDs and EpiZips as novel therapeutic targets
- Precision genomic control with tunable and durable effect with the potential to re-dose
- Single and/or multiple gene control with a single therapeutic
- Ability to multiplex within or across IGDs for synergistic effect
- No changes in nucleic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

Our Portfolio

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

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

Our pipeline consists of the following programs:



Regenerative Medicine

We are developing OEC candidates to up-regulate the expression of HNF4a, a transcriptional master regulator, as a potential way to restore liver-cell function in patients with severe liver dysfunction. In preclinical animal studies, we have observed durable increases in HNF4a and significant improvements in liver histology *in vivo*.

We are also developing OEC candidates to control the expression of genes that have been strongly linked to cell-growth inhibition in patients with diabetes and other conditions to restore the capacity for corneal regeneration.

Multigenic Diseases Including Immunology

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

We are also developing OEC candidates to control expression of genes implicated in patients with idiopathic pulmonary fibrosis to halt or reverse disease progression and improve disease outcomes.

Oncology

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

We are also developing OEC candidates for the treatment of NSCLC and small cell lung cancer. In preclinical studies in NSCLC xenografts in a mouse subcutaneous tumor model, we observed a 63% inhibition of tumor growth following administration of an OEC candidate compared to control.

Select Monogenic Diseases

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

Our Strategy

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

Our strategy includes:

- Strategically invest in and advance the OMEGA platform.
- Establish OECs as a new class of transformative medicine.
- Expand our pipeline through internal and collaboration efforts.
- Build a fully integrated digitalized biopharmaceutical company.
- Curate world-class talent and culture.

Our Team

We have built a world-class team of talented and highly experienced leaders to set and execute our strategy in fulfillment of our vision of pioneering the development of a new class of epigenetic medicines. Our leadership team has more than 100 years of combined experience in the pharmaceutical and biotechnology industry, has been involved in filing more than 30 INDs and 20 submissions for product approval, and has launched more than 30 pharmaceutical products globally. Mahesh Karande, our Chief Executive Officer, has a track record of leading biopharmaceutical businesses across the discovery, preclinical- and clinical-development, commercialization, and product-life-cycle-management stages to drive portfolio value and company growth. He previously served as President and Chief Executive Officer of Macrolide Pharmaceuticals, led Novartis

Oncology's solid tumor franchise in the United States, and held several senior leadership roles at Novartis across the globe. Our Chief Scientific Officer, Thomas McCauley, Ph.D., has over 21 years of experience in the biopharmaceutical industry building and leading research-and-development organizations at the forefront of advanced genetic therapies across therapeutic areas and has made key contributions to the development, global registration, approval and life-cycle management of more than ten marketed products. He previously served as the Chief Scientific Officer of Translate Bio and Macrolide Pharmaceuticals. Our Chief Financial Officer, Roger Sawhney, M.D., has over 25 years of financial and strategic expertise, ranging from global investments in the healthcare sector to business and strategy development in the biopharmaceutical industry. He previously served as the Head of Global Corporate Strategy for Novartis AG. We have also assembled a scientific advisory board of leaders with deep expertise in genomics, epigenetics, and chromatin biology, as well as target biology and clinical development experience.

Our Beginnings: Omega Therapeutics and Flagship Pioneering

Flagship Pioneering, or Flagship, founded Omega Therapeutics in 2017 as VL42, Inc. The Flagship origination team, led by Dr. David Berry, working together with Dr. Noubar Afeyan, CEO of Flagship, set out to more fully understand epigenetic regulation and non-genetically alter it through experimentation at Flagship Labs. VL42 was based on an exploration posing the question: "What if epigenetics worked through a universal operating system and what if we could interrogate that system and therapeutically intervene?" This exploration yielded critical insights on epigenomics, including intervention points and the use of controllers as a means to control the expression of one or more coordinated genes. We created Omega Therapeutics to develop a platform to design and make a new category of medicines, one that can harness the potential of IGDs and epigenetic control, and lead to the treatment of important diseases with high unmet medical needs. As part of creating Omega Therapeutics, Flagship complemented its own epigenomic patent estate licensed to Omega Therapeutics with exclusive licenses to patent estates in epigenetics from the Whitehead Institute at the Massachusetts Institute of Technology (Dr. Rudolf Jaenisch's lab and Dr. Richard Young's Lab).

Since inception, we have raised approximately $200 million from Flagship as well as major mutual funds, healthcare-dedicated funds, and other leading investors.

Summary Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks 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.
- Even if we consummate this offering, we will 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.
- As a result of our history of losses and negative cash flows from operations, our financial statements contain a statement regarding a substantial doubt about our 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 a have a material adverse impact on our platform or our business.
- Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.
- Due to increased demand for the manufacture of mRNA- and LNP-based vaccines to treat COVID-19, our ability to manufacture our product candidates for preclinical or clinical supply could be limited, which could adversely affect our development plans.
- Our OEC candidates are based on novel technology and may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping.
- We must adapt to rapid and significant technological change and respond to introductions of new products and technologies by competitors to remain competitive.
- We will rely on third parties for the foreseeable future for the manufacture of materials for our research programs, preclinical studies and clinical trials and we do not have long-term contracts with many of these parties.
- We are planning to acquire and establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on contract development and manufacturing organizations for the manufacture of our product candidates, which will be costly, time-consuming, and which may not be successful.
- We have a limited number of suppliers for the lipid excipients used in our product candidates and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our product candidates. If we obtain regulatory approval for any of our product candidates, we would need to expand the supply of lipid excipients in order to commercialize them.
- We are very early in our development efforts. All of our product candidates are in preclinical development or discovery and it will be many years before we commercialize a product candidate, if ever. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

- If we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks you should consider before making an investment in our common stock, see "Risk factors."

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- the option to present only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; 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 may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if any of the following events occur prior to the end of such five-year period, (i) our annual gross revenue exceeds $1.07 billion, (ii) we issue more than $1.0 billion of non-convertible debt in any three-year period or (iii) we become a "large accelerated filer" (as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act), we will cease to be an emerging growth company prior to the end of such five-year period. We will be deemed to be a "large accelerated filer" at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of $700.0 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act, for a period of at least 12 months and (c) have filed at least one annual report pursuant to the Exchange Act.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other

reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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.

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.

Corporate Information

We were incorporated under the laws of the State of Delaware in July 2016 under the name VL42, Inc. Our principal executive offices are located at 20 Acorn Park Drive, Cambridge, Massachusetts 02140 and our telephone number is 617-949-4360. Our website address is *www.omegatherapeutics.com. The information contained in, or accessible through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.*

The Offering

Common stock offered by us	shares
Option to purchase additional shares	The underwriters have a 30-day option to purchase up to additional shares of our common stock at the public offering price less estimated underwriting discounts and commissions.
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase additional shares of our common stock), at an assumed public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. We anticipate that we will use the net proceeds of this offering for continued research and development of our portfolio of OECs, including preclinical studies and advancement through potential preclinical proof-of-concept of our lead programs; for IND-enabling studies and the potential initiation of clinical studies for certain of our current programs; for continued advancement of our platform technologies and discovery-stage research for other potential programs; to lease and build out a facility to manufacture drug substance and drug product for clinical needs; and for working capital and general corporate purposes. See “Use of Proceeds” beginning on page 89 for additional information.
Risk factors	You should carefully read the “Risk Factors” beginning on page 14 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	“OMGA”

The number of shares of our common stock to be outstanding after this offering is based on shares of our common stock outstanding as of , 2021, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of shares of common stock, and excludes:

- shares of our common stock issuable upon exercise of stock options outstanding under our 2017 Equity Incentive Plan, or the 2017 Plan as of , 2021, at a weighted-average exercise price of $ per share;
- shares of our common stock reserved for future issuance under our 2021 Incentive Award Plan, or the 2021 Plan, which will become effective in connection with this offering, and shares of our common stock that become available pursuant to provisions in the 2021 Plan that automatically increase the share reserve under the 2021 Plan;
- shares of our common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, which will become effective in connection with this offering, and shares of our common stock that become available pursuant to provisions in the 2021 ESPP that automatically increase the share reserve under the 2021 ESPP; and
- shares of our common stock issuable upon the exercise of a warrant to purchase shares of our Series A preferred stock that will become a warrant to purchase shares of our common stock, at an exercise price of $ per share, upon the closing of this offering.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- a -for- stock split of our common stock, which will become effective prior to the effectiveness of the registration statement of which this prospectus forms a part;
- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of shares of our common stock upon the closing of this offering;
- the outstanding warrant to purchase our Series A preferred stock becoming a warrant to purchase our common stock upon the closing of this offering;
- no exercise of the outstanding warrant described above;
- no exercise of outstanding options after , 2021;
- no exercise by the underwriters of their option to purchase additional shares of our common stock; and
- the filing of our restated certificate of incorporation, which will occur after the closing of this offering.

Summary Financial Data

The following tables set forth our summary financial data as of, and for the periods ended on, the dates indicated. We have derived the statements of operations and comprehensive loss data for the years ended December 31, 2020 and 2019 from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data presented below for the three months ended March 31, 2021 and 2020 and the summary balance sheet data as of March 31, 2021 have been derived from our unaudited financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial information in those statements. In the opinion of management, the unaudited data reflect all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that should be expected for any future period. You should read the following summary financial data together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

	Year ended December 31,		Three months ended March 31,	
	2020	2019	2021	2020
	(in thousands, except share and per share data)			
Statements of operations and comprehensive loss data:				
Operating expenses:			$	$
Research and development	$ 21,063	$ 11,931		
General and administrative	6,236	4,227		
Related party expense, net	1,346	1,181		
Total operating expenses	28,645	17,339		
Loss from operations	(28,645)	(17,339)		
Other expense, net:				
Interest expense, net	(777)	(595)		
Other expense, net	(25)	(11)		
Total other expense, net	(802)	(606)		
Net loss and comprehensive loss	$ (29,447)	$ (17,945)	$	$
Net loss per common stock attributable to common stockholders, basic and diluted	$ (2.00)	$ (1.43)	$	$
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	14,756,671	12,538,575		
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)(1)		$		$
Pro forma weighted-average common stock outstanding—basic and diluted (unaudited)(1)				

(1) The unaudited pro forma basic and diluted weighted-average common stock outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 and the three months ended March 31, 2021 have been prepared to give effect, upon a qualified initial public offering, to the automatic conversion of all outstanding shares of redeemable convertible preferred stock into common stock as if the proposed initial public offering had occurred on the later of the beginning of each period or the issuance date of the redeemable convertible preferred stock.

	As of March 31, 2021		
	Actual	Pro Forma(2)	Pro Forma As Adjusted(3) (4)
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$	$	$
Working capital(1)			
Total assets			
Total liabilities			
Redeemable convertible preferred stock			
Additional paid-in capital			
Accumulated deficit			
Total stockholders' equity (deficit)			

(1) We define working capital as current assets less current liabilities. See our financial statements for further details regarding our current assets and current liabilities.

(2) The pro forma balance sheet data gives effect to the:
- automatic conversion of all outstanding shares of our preferred stock into an aggregate of shares of our common stock upon the closing of this offering; and
- the outstanding warrant to purchase an aggregate of shares of our Series A preferred stock becoming a warrant to purchase number of shares of our common stock upon the closing of this offering.

(3) Reflects the pro forma adjustments described in footnote (2) and the issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets, additional paid-in capital and total stockholders' equity (deficit) by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares of our common stock offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, total assets, additional paid-in capital and total stockholders' equity (deficit) by $ million. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

RISK FACTORS

You should carefully consider the risks and uncertainties described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before making an investment in our common stock. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to Our Financial Condition and Capital Requirements

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

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

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

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

We have incurred significant net losses since our inception, including net losses of $ million, $29.4 million, and $17.9 million for the three months ended March 31, 2021 and the years ended December 31, 2020 and 2019, respectively. As of March 31, 2021, we had an accumulated deficit of $ million. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our preclinical development activities and preparing for clinical trials of our product candidates.

We expect to continue to incur significant additional net losses for the foreseeable future as we seek to advance product candidates through clinical development, continue preclinical development, expand our research and development activities, develop new product candidates, complete preclinical studies and clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. In order to obtain United States Food and Drug Administration, or FDA, approval to market any product candidate in the United States, we must submit to the FDA a Biologics

License Application, or BLA, demonstrating to the FDA's satisfaction that the product candidate is safe and effective for its intended use(s). Foreign regulatory authorities impose similar requirements. This demonstration requires significant research and extensive data from animal tests, which are referred to as nonclinical or preclinical studies, as well as human tests, which are referred to as clinical trials. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial and difficult to accurately predict. Because of the numerous risks and uncertainties associated with the development of drug products, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. Our expenses will also increase substantially if or as we:

- continue our research and development efforts and submit INDs 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
- 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.

Even if we consummate this offering, we will 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.

Even after the consummation of this offering, we will continue to need additional capital beyond the proceeds of this 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.

As of March 31, 2021, we had cash and cash equivalents of $ million. We estimate that our net proceeds from this offering will be approximately $ million, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The net proceeds from this offering and our existing cash and cash equivalents will not be sufficient to fund all of our efforts that we plan to undertake.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements . This estimate is based on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We will require significant additional funds in order to launch and commercialize our current and any future product candidates. In addition, other unanticipated costs may arise in the course of our development efforts. Because all of our product candidates are in preclinical development and we have not conducted any clinical trials, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results, and costs of our preclinical studies and any future clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for our current and future product candidates in regions where we choose to commercialize any products;
- the number of future product candidates and potential additional indications that we may pursue and their development requirements;
- the stability, scale, yield, and cost of our manufacturing process as we scale-up production and formulation of our product candidates for clinical trials, in preparation for regulatory approval and in preparation for commercialization, including our ability to build our own manufacturing facility;
- the costs of 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.

As a result of our recurring losses from operations and recurring negative cash flows from operations, and because we have not yet obtained additional capital in connection with this offering, our financial statements contain a statement regarding a substantial doubt about our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. See the risk factor below titled, “As a result of our history of losses and negative cash flows from operations, our financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.” If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause additional dilution to our stockholders, including purchasers of common stock in this offering, 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, 2020, we had $12.0 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 December 31, 2023, and we will be required to begin repayment of the loan in 24 equal monthly payments beginning on December 31, 2021. The outstanding balance under the Loan Agreement bears interest at a floating annual rate equal to the greater of (i) 0.75% above the prime rate then in effect and (ii) 6.00%, due monthly starting the first month after December 30, 2020. Pursuant to the terms of the Loan Agreement, interest payment on the outstanding term loan is less than $0.1 million per month, and we are required to pay a success fee of $0.2 million upon the occurrence of a specified liquidity event, including the completion of this offering. 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 lenders 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 revenue and may never be profitable.

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

As a result of our history of losses and negative cash flows from operations, our financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.

A history of operating losses and negative cash flows from operations combined with our anticipated use of cash to fund operations raises substantial doubt about our ability to continue as a going concern beyond the 12-month period from the issuance date of our audited financial statements for the year ended December 31, 2020. Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities or to raise additional capital to finance our operations.

There is no assurance that we will succeed in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence by investors and employees. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our investors will lose all or a part of their investment.

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

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

Our success depends on the OMEGA platform technology which is a novel technology. As such, it is difficult to accurately predict the preclinical and clinical developmental challenges we may incur for our programs and product candidates as they proceed through product discovery or identification, preclinical studies, and clinical trials. In addition, because we have not commenced clinical trials of any of our pipeline product candidates, we have not yet been able to assess the safety or efficacy of our technology in humans and there may be short-term or long-term effects from treatment with any product candidates that we develop that we cannot predict at this time. Also, animal models may not exist for some of the diseases we choose to pursue in our programs. Given the novelty of our technology platform, there can be no assurance as to the length of preclinical work, clinical development, the number of patients that FDA or comparable foreign regulatory authority may require to be enrolled in clinical trials to establish the safety and efficacy, purity and potency of our product candidates, or that the data generated in these clinical trials will be acceptable to the FDA or comparable foreign regulatory authorities to support marketing approvals. The FDA and comparable regulatory authorities may take longer than usual to come to a decision on any biologics license application, or BLA, or foreign marketing application, that we submit and may ultimately determine that there is not adequate data, information, or experience with our product candidate to support approval. The FDA or comparable foreign regulatory authorities may also require that we conduct additional post-marketing studies or implement risk management programs, such as a risk evaluation and mitigation strategy, or REMS, 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. As a result of these factors, it is difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of the OMEGA platform technology, or any similar or competitive epigenetic technologies, will result in the identification, development, and regulatory approval of any products. There can be no assurance that any development challenges we experience in the future related to the OMEGA platform technology or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use as well as market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities and approaches. Further, as we are developing novel treatments, there is heightened risk that the FDA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, few gene therapy products have been approved by the FDA and comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union, or EU, or other jurisdictions. Further, approvals by one regulatory authority may not be indicative of what other regulatory authorities may require for approval.

Regulatory requirements governing programmable epigenetic medicines have evolved and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In addition to FDA oversight and oversight by IRBs, under guidelines promulgated by the National Institutes of Health, or NIH, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical study can begin at any institution, that institution's IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. These and other regulatory review agencies, committees, and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. Similar requirements apply in the EU. The European Medicines Agency, or the EMA, has a Committee for Advanced Therapies, or CAT, that is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products, or ATMP(s). ATMPs include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered

medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for ATMP candidate that is submitted to the EMA. In the EU, the development and evaluation of an ATMP must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape.

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

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

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

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

- discovery efforts at identifying potential epigenomic controller medicines may not be successful;
- nonclinical or preclinical study results may show potential epigenomic controller medicines to be less effective than desired or to have harmful or problematic side effects;
- clinical trial results may show the epigenomic controller medicines to be less effective than expected (e.g., a clinical trial could fail to meet one or more endpoints) or to have unacceptable side effects or toxicities;
- adverse effects in any one of our preclinical studies or clinical trials or adverse effects relating to our mRNA, or lipid nanoparticles, or LNPs, may lead to delays in or termination of one or more of our programs; and
- the insufficient ability of our translational models to reduce risk or predict outcomes in humans, particularly given that each component of our investigational medicines and development candidates, may have a dependent or independent effect on safety, tolerability, and efficacy, which may, among other things, be species-dependent.

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

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

All of our programs are in preclinical development and we have identified only one lead development candidate to date. Before we can initiate clinical trials for a development candidate, we must complete extensive preclinical studies, including IND-enabling good laboratory practices, or GLP, 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 filing. CMC activities for a new class of medicines such as epigenomic controllers require extensive manufacturing processes and analytical development, which is uncertain and lengthy. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies, and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, time-consuming, and subject to uncertainty. A failure of one or more clinical trials can occur at any stage of the process, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data

are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

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

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on trial design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- delays in obtaining required institutional review board, or IRB, or ethics committee approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating, 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 ethics committees or 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.

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation, or interpretation of results of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective, pure, and potent for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required for approval by the FDA or comparable foreign regulatory authorities;
- serious and unexpected product candidate-related side effects experienced by participants in our clinical trials or by individuals using products similar to our product candidates;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or other submission, or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may disagree regarding the formulation, labeling, and/or the specifications of our product candidates;
- our clinical sites, investigators or other participants in our clinical trials may deviate from a trial protocol, fail to conduct the trial in accordance with regulatory requirements, or drop out of a trial;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

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

Even if we eventually complete clinical trials and obtain approval of a BLA or foreign marketing application for our product candidates, the FDA, or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional trials, including Phase 4 clinical trials, and/or the implementation of a REMS, 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 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 manufacturing validation 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. 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 after this offering.

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

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

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

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

- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

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

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

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

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

In addition to using our platform for the discovery and development of our own product candidates, we collaborate with other biopharmaceutical and pharmaceutical companies in the discovery and development of our OEC. The technological landscape around artificial intelligence and precision drug design is are 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 the 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 apply for FDA fast track designation. A product candidate may be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A product candidate may receive RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such condition. While we may seek fast track, breakthrough, and/or RMAT designation, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track, breakthrough, or RMAT designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw fast track, breakthrough, or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track, breakthrough, and/or RMAT designation alone do not guarantee qualification for the FDA's priority review procedures.

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 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 ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA 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, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, there have been significant disruptions due to the ongoing COVID-19 pandemic. Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections and resumed inspections in China and India in early 2021. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should FDA determine that an inspection is necessary for approval and an

inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be appropriate, the agency has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, as of March 18, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. However, the FDA may not be able to continue its current pace and approval timelines could be extended. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt 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.

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.

We also expect that operating as a public company 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. The United States Supreme Court is currently reviewing the constitutionality of the ACA in its entirety. Although the U.S. Supreme Court has not yet ruled, 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 the Supreme Court ruling, other such litigation and any other healthcare reform measures of the Biden administration will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional

reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

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

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

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

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

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

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

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

If the FDA or other regulatory authorities approve any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and record-keeping of our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of biological products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities to ensure compliance with cGMP regulations and similar standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, any regulatory approvals that we may receive for our product candidates may contain significant limitations related to use restrictions for specified age groups, warnings, precautions, or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training, and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools.

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

- delays in reviewing or the rejection of product applications or supplements to approved applications;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- warning or untitled letters;
- civil or criminal penalties;
- injunctions;

- suspension or withdrawal of regulatory approvals;
- product seizures, detentions, or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on our operations, including costly new manufacturing requirements.

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

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

In addition, the EU has adopted the Clinical Trials Regulation, or CTR, in April 2014, which is expected to become applicable by early 2022. The CTR will be directly applicable in all EU member states, repealing the current Clinical Trials Directive. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new CTR becomes applicable. The extent to which ongoing clinical trials will be governed by the CTR will depend on when the CTR becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the CTR becomes applicable the CTR will at that time begin to apply to the clinical trial. The CTR harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which will notably contain a centralized EU portal and database.

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 our 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 other healthcare providers starting in 2022, 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, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the EU and the European Economic Area, or EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland), Regulation (EU) 2016/679, known as the General Data Protection Regulation, or GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. 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 new disclosures to California individuals and affording such individuals new abilities to opt out of certain sales of personal information, and provides for civil penalties for violations as well as a private right of action for data breaches that is expected to increase data breach litigation. 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 business associates 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.

The privacy laws in the EU have been significantly reformed in recent years. On May 25, 2018, the GDPR came into effect and imposes strict requirements for processing the personal data of

individuals within the EEA. The GDPR is directly applicable in each EU member state and is extended to the EEA. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR applies extraterritorially, requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for collecting and processing personal data (including data from clinical trials), requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training, and data audit. The GDPR provides that EEA countries may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union, or CJEU. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain.

Additionally, following the United Kingdom's withdrawal from the EU, which is commonly referred to as Brexit, beginning in 2021 we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million (£17.5 million) or 4% of global turnover for violations. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU member states to the United Kingdom for a four-year period, subject to subsequent extensions. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations, and financial condition.

We cannot assure you that our 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. 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, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, 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. Even when HIPAA does not apply, according to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size, and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations. As such, we may be subject to state laws, including the CCPA, requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR and legislation of the EEA countries implementing it.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the EEA into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health information.

Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party CDMOs, CROs, or other contractors or consultants fail to comply with applicable federal, state, or local regulatory privacy requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing, and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability,

breaches of data security, or reputational damage. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

Risks Related to Commercialization

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

We are very early in our development efforts and have focused our research and development efforts to date on developing the OMEGA platform, identifying our initial targeted disease indications and engineering our initial OECs. We have only achieved preclinical proof-of-concept *in vivo* for some of our programs and there is no guarantee that we will achieve it 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 and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests, the start of our first clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect.

Commercialization of our product candidates will require additional preclinical and clinical development and regulatory and marketing approval. Our ability to conduct development or attain marketing approval will depend on the sufficiency of our financial and other resources to complete the necessary preclinical studies, IND-enabling studies, and clinical trials and the successful enrollment in, and completion of, clinical trials.

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

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

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

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

If these competitors access the marketplace before we do with safer, more effective, or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products, or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will

depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing, and selling commercial quantities of potential products.

While we are not aware of other companies developing epigenomic controllers, we 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., Constellation Pharmaceuticals, Inc., CRISPR Therapeutics AG, Editas Medicine, Inc., Epizyme, Inc., Intellia Therapeutics, Inc., Ionis Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., Pfizer Inc., and Sangamo Therapeutics, Inc. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians, or patients. Hospitals, physicians, or patients may conclude that our products are less safe or effective or otherwise less attractive than existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Many of our competitors have substantially greater capital resources, robust product candidate pipelines, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. As a result, our competitors may achieve product commercialization or patent or other intellectual property protection earlier than we can. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified clinical, regulatory, scientific, sales, marketing, and management personnel, and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or noncompetitive.

Our product candidates may face competition sooner than anticipated.

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

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may

impact the BPCIA exclusivity provisions, have also been the subject of litigation. 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; 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 and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no

assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition, or results of operations.

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

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

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

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

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

Risks Related to our Dependence on Third Parties and Manufacturing

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

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

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

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

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

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

Our product and product intermediates are extremely temperature sensitive, and we may learn that any or all of our products are less stable than desired. We may also find that transportation

conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our OEC candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions.

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

We will rely on third parties for the foreseeable future for the manufacture of materials for our research programs, preclinical studies and clinical trials and we do not have long-term contracts with many of these parties. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

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

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

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;

- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation or unauthorized disclosure of our intellectual property or other proprietary information, including our trade secrets and know-how.

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

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

We have entered into a letter of intent to lease a facility with approximately 53,000 square feet of space to buildout a manufacturing facility located in the Northeastern United States as an alternative or in addition to our reliance on CDMOs for the manufacture of drug substance and drug product for preclinical and clinical needs. If the lease is entered into, we plan to renovate and customize the manufacturing facility for our use. We expect that construction of our own manufacturing facility will provide us with enhanced control of material supply for preclinical studies, clinical trials, and commercialization, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience as a company in construction of a manufacturing facility and may never be successful in building our own manufacturing facility or capability. As a result, we will also need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, manufacture and eventual commercialization, if approved, of our product candidates. We, as a company, have no experience in setting up, building, or eventually managing a manufacturing facility. If we failed to select the correct location, or if we fail to enter into the lease agreement, or fail to complete the planned renovation and customization in an efficient manner, or fail to recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the FDA, the EMA, 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, the EMA, 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 product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects. Problems in our manufacturing process could restrict our ability to meet clinical and market demand for our products.

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

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

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

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

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

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

We have a limited number of suppliers for the lipid excipients used in our product candidates and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our

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

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

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

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

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

Any third parties conducting our planned clinical trials or preclinical studies are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our planned clinical trials may be extended, delayed, or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities that could harm our competitive position. In addition, principal investigators for our planned clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash and cash equivalents or equity compensation

in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any BLA we submit to the FDA, or any comparable foreign regulatory applications we submit to foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing our product candidates.

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

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

We may seek collaborative relationships for the development and commercialization of our product candidates. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate product revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into. Collaborations involving our product candidates pose the following risks to us:

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

- collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished, or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, devices, materials, know-how, or intellectual property of the collaborator relating to our product candidates;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short- and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations from other companies with substantially greater financial, marketing, sales, technology, or other business resources. Business combinations among biotechnology and pharmaceutical companies have also resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to

exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

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

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

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

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

Risks Related to Intellectual Property

If we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property and prevent others from duplicating our pipeline product candidates, or their use or manufacture, or any of and any future product candidates, and our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to such product candidates.

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

The strength of patents in the biotechnology and pharmaceutical field involves complex legal, factual, and scientific questions and can be uncertain. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been

found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge the inventorship, ownership, validity, enforceability, or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Additionally, any U.S. provisional patent application that we file is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent application, we may lose our priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application.

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

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

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our patents may be challenged in courts or patent offices in the United States and abroad. In addition, the issuance of a patent does not give us the right to practice the patented invention, as third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology.

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

The Leahy-Smith Act created for the first time new procedures to challenge issued patents in the United States, including post-grant review, *inter partes* review and derivation proceedings, which are adversarial proceedings conducted at the USPTO, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, which all of our patent filings have, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas *inter partes* review proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the USPTO include review of patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts. The USPTO issued a final rule effective November 13, 2018 announcing that it will now use the same claim construction standard currently used in the U.S. federal courts to interpret patent claims in USPTO proceedings, which is the plain and ordinary meaning of words used. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us, including loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

As a result of all of the foregoing, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Our commercial success depends in part on our avoiding actual and allegations of infringement, misappropriation or other violation of the patents and other proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, re-examination, and post-grant and *inter partes* review proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the European Patent Office, or EPO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Many companies in intellectual property-dependent industries, including the pharmaceutical industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. As biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to composition of matter, drug delivery, methods of manufacture or methods for treatment related to the use or manufacture of our

product candidates. We cannot guarantee that our technologies, products, compositions, and their uses do not or will not infringe, misappropriate or otherwise violate third-party patent or other intellectual property rights. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any third-party patents were held by a court of competent jurisdiction to cover the composition of matter of any of our product candidates, the manufacturing process of any of our product candidates or the method of use for any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, which may not be available at all or on commercially reasonable terms, or until such patents expire.

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates and/or harm our reputation and financial results. Defense of these claims, regardless of their merit, could involve substantial litigation expense and could be a substantial diversion of management and employee resources from our business. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, in the case of claims concerning registered trademarks, rename our product candidates, or obtain one or more licenses from third parties, which may require substantial time and monetary expenditure, and which might be impossible or technically infeasible. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the

commercial marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the EU, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

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

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

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

with Flagship, WIBR, and Acuitas, including each licensor's termination rights, please see "Business –License Agreements."

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

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

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

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

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Additionally, if we fail to comply with our obligations under any future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing, or

marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

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

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

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

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

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

Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities.

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

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

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

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

We are highly dependent on our management, including our Chief Executive Officer, Mahesh Karande, our Chief Scientific Officer, Thomas McCauley, and our Chief Financial Officer, Roger Sawhney. 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, particularly after the expiration of the lock-up agreements described in this prospectus.

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

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

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

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, surfaced in Wuhan, China. Since then, COVID-19 has spread globally. Our principal executive offices and laboratory space are located in Cambridge, Massachusetts. The Commonwealth of Massachusetts initially responded to the COVID-19 pandemic by issuing stay-at-home orders. Since then, Massachusetts has under-gone a phased re-opening, which is nearly complete. In response to public health directives and to help reduce the risk to our employees, we took precautionary measures, including implementing work-from-home policies for our administrative employees and staggered work times for our lab employees. We plan to continue these measures and are assessing when and how to resume normal operations. The COVID-19 pandemic continues to evolve, and we cannot predict how new executive orders or other preventative measures, if any, could impact our ability to conduct our business and our product candidate development programs. Any severe disruptions in our operations as a result could negatively impact our business, results of operations, and financial condition.

In addition, quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related

to COVID-19 or other infectious diseases have impacted and may continue to impact our third-party service providers.

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

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

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

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

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

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

Risks Related to Our Common Stock and this Offering

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. Although we intend to apply to have our common stock listed on the Nasdaq Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

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 or above the initial public offering price. 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;
- 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 and elsewhere in this prospectus.

In addition, the stock market in general, and the Nasdaq Global Market 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. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. 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.

After this offering, 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.

Upon the closing of this offering, based on the number of shares of common stock outstanding as of , our executive officers, directors, and stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates will, in the aggregate, hold shares representing approximately % of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares). 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.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent shares subsequently are issued under outstanding options or warrants, you will incur further dilution. Based on an assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus), you will experience immediate dilution of $ per share as of , 2021, representing the difference between our pro forma as adjusted net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately % of the aggregate price paid by all purchasers of our stock but will own only approximately % of our common stock outstanding after this offering.

This dilution is due to our investors who purchased shares of our stock prior to this offering, having paid substantially less when they purchased their shares than the price offered to the public in this offering. To the extent that outstanding stock options or warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares of common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section entitled "Dilution."

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We anticipate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, for continued research and development of our portfolio of OECs, including preclinical studies and advancement through potential preclinical proof-of-concept of our lead programs; for IND-enabling studies and the potential initiation of clinical studies for certain of

our current programs; for continued advancement of our platform technologies and discovery-stage research for other potential programs; to lease and build out a facility to manufacture drug substance and drug product for clinical needs; and for working capital and general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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. After this offering, we will have outstanding shares of common stock based on the number of shares outstanding as of , 2021. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. The remaining shares are currently restricted as a result of securities laws or lock-up agreements (which may be waived, with or without notice, pursuant to the terms of such lock-up agreement), but will become eligible to be sold at various times beginning 180 days after this offering, unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended, or Rule 144. Moreover, after this offering, holders of an aggregate of shares of our common stock will 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 intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

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 this offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common shares that are held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;

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

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

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

We will 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global 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 will need to devote 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, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and

officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, in our second annual report due to be filed with the SEC after becoming a public company, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company or a low-revenue smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We may discover significant deficiencies or material weaknesses in our internal control over financial reporting, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our 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 not currently required to comply with the rules of the SEC implementing Section 404 and, therefore, we are not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act of 2002, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Although we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. As an emerging growth company and a low-revenue smaller reporting company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC or the date 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 will need to undertake 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.

Upon the closing of this offering, we will become 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 do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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 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 restated certificate of incorporation and our restated bylaws, which will become effective upon the closing of this offering 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 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 restated certificate of incorporation will designate 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 restated certificate of incorporation, which will become effective upon the closing of this offering, 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 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 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. 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 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 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, 2020, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $63.6 million and $62.6 million, respectively, which may be available to offset future taxable income, if any. As of December 31, 2020, we also had federal and state research and development credit carryforwards of $1.4 million and $1.3 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 in connection with or after this offering, 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 would suffer in the event of system failures, deficiencies, or intrusions.

Our computer 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, unauthorized access or

other cybersecurity attacks, natural disasters (including hurricanes), terrorism, war, fire, and telecommunication or electrical failures. In the ordinary course of our business, we directly or indirectly collect, store, and transmit sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data, and personally identifiable health 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 employee error, 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 not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, or breaches in our systems or those of our CROs and other contractors and consultants.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical studies or clinical trial data from completed, ongoing, or planned studies or trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential, or proprietary information, we could incur liability and the further development of our product candidates could be delayed. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, or stolen.

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

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

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

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

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

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

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

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product candidate development, prospective products, product candidate approvals, research and development activities and costs, future revenue, timing and likelihood of success of our business plans, plans and objectives of management, future results and timing of clinical trials, treatment potential of our product candidates, and the market potential of our product candidates are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “would” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this prospectus 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 prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. 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. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.

MARKET AND INDUSTRY DATA

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. Management’s estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. While we believe our internal company research as to such matters is reliable and appropriate, such research has not been verified by any independent source. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates.

USE OF PROCEEDS

We estimate that the net proceeds to us from our issuance and sale of shares of our common stock in this offering will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds will be approximately $ million.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by $ million, assuming the assumed initial public offering price stays the same.

We anticipate that we will use the net proceeds of this offering, together with our existing cash and cash equivalents, for the following purposes:

- approximately $ million for continued research and development of our portfolio of OECs, including preclinical studies and advancement through potential preclinical proof-of-concept of our lead programs;
- approximately $ million for IND-enabling studies and the potential initiation of clinical studies for certain of our current programs;
- approximately $ million for continued advancement of our platform technologies and discovery-stage research for other potential programs; and
- approximately $ million to lease and build out a facility to manufacture drug substance and drug product for clinical needs.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of our product candidates. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from preclinical studies and clinical trials, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds of this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements . We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently

expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources. We could use our available capital resources sooner than we currently expect, in which case we would need to obtain additional funding, which may not be available to use on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term and intermediate-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for the operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, contractual requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, the terms of our existing loan and security agreement with Pacific Western Bank preclude us from paying dividends on our equity securities without Pacific Western Bank's consent.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2021, as follows:

- on an actual basis;
- on a pro forma basis to reflect:
  - the automatic conversion of all outstanding shares of our preferred stock into shares of our common stock upon the closing of this offering;
  - the outstanding warrant to purchase an aggregate of shares of our Series A preferred stock becoming a warrant to purchase number of shares of our common stock upon the closing of this offering; and
  - the filing and effectiveness of our amended and restated certificate of incorporation.
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus and the “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and other financial information contained in this prospectus.

	As of March 31, 2021 (in thousands, except share and per share data)		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
Cash and cash equivalents	$	$	$
Preferred stock warrant liability			
Long-term debt, net of current portion			
Convertible preferred stock (Series A, B and C), par value $0.001 per share; 132,858,564 shares authorized, 131,008,559 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Stockholders' (deficit) equity			
Preferred stock, $0.001 par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, par value $0.001 per share; 175,000,000 shares authorized, 17,173,168 shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted			
Additional paid in capital			
Accumulated deficit			
Total stockholders' (deficit) equity			
Total capitalization	$		$

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid in capital, total stockholders' equity (deficit) and total capitalization by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price per share would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million.

The number of shares in the table above excludes:

- shares of our common stock issuable upon the exercise of stock options outstanding under the 2017 Plan, as of , 2021, at a weighted-average exercise price of $ per share;
- shares of our common stock reserved for future issuance under our 2021 Plan, which will become effective in connection with this offering, and shares of our common stock that become available pursuant to provisions in the 2021 Plan that automatically increase the share reserve under the 2021 Plan;

- shares of our common stock reserved for future issuance under our 2021 ESPP, which will become effective in connection with this offering, and shares of our common stock that become available pursuant to provisions in the 2021 ESPP that automatically increase the share reserve under the 2021 ESPP; and
- shares of our common stock issuable upon the exercise of a warrant to purchase shares of our Series A preferred stock that will become a warrant to purchase shares of our common stock, at an exercise price of $ per share, upon the closing of this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of March 31, 2021, we had a historical net tangible book value of $ million, or $ per share of common stock. Our historical net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of March 31, 2021.

Our pro forma net tangible book value as of March 31, 2021 was $ million, or $ per share. Pro forma net tangible book value represents the amount of our total tangible assets less total liabilities, after giving effect to the automatic conversion of all shares of our preferred stock outstanding as of March 31, 2021 into an aggregate of shares of our common stock in connection with this offering. Pro forma net tangible book value per share represents our pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2021, after giving effect to the pro forma adjustment described above.

After giving further effect to receipt of the net proceeds from our issuance and the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been $ million, or $ per share. This amount represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution of approximately $ per share to new investors participating in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock. The following table illustrates this dilution:

Assumed initial public offering price per share		$
Historical net tangible book value per share as of March 31, 2021	$	
Increase (decrease) per share attributable to the pro forma adjustment described above		
Pro forma net tangible book value (deficit) per share as of March 31, 2021		
Increase per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after this offering		$
Dilution per share to new investors in this offering		$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by $ million, and dilution in pro forma net tangible book value per share to new investors by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by $ per share and decrease (increase) the dilution to new investors by $ per share, assuming that the assumed initial public offering price remains the

same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be $ per share, the increase in pro forma net tangible book value per share would be $ and the dilution to new investors would be $ per share, in each case assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

The following table summarizes on the pro forma as adjusted basis described above, as of March 31, 2021, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and new investors paid. The calculation below is based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders		%	$	%	$
New investors					
Total		100.0%		100.0%	$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming no change in the assumed initial public offering price.

The foregoing tables and calculations exclude:

- shares of our common stock issuable upon the exercise of stock options outstanding, pursuant to the 2017 Plan, as of , 2021 at a weighted-average exercise price of $ per share;
- shares of our common stock reserved for future issuance under our 2021 Plan, which will become effective in connection with this offering, and shares of our common stock that become available pursuant to provisions in the 2021 Plan that automatically increase the share reserve under the 2021 Plan;
- shares of our common stock that will become available for future issuance under our 2021 ESPP, which will become effective in connection with this offering, and shares of our common stock that become available pursuant to provisions in the 2021 ESPP that automatically increase the share reserve under the 2021 ESPP; and

- shares of our common stock issuable upon the exercise of a warrant to purchase shares of our Series A preferred stock that will become a warrant to purchase shares of our common stock, at an exercise price of $ per share, upon the closing of this offering.

To the extent that any outstanding options are exercised or new options are issued under our incentive award plans, or we issue additional shares of common stock or other securities convertible into or exercisable or exchangeable for shares of our capital stock in the future, there will be further dilution to investors participating in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, 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 prospectus, 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 prospectus.

Overview

At Omega Therapeutics, our goal is to pioneer a new class of DNA-sequence-targeting, mRNA-encoded therapeutics to fundamentally transform human medicine in the service of patients. Our pioneering OMEGA Epigenomic Programming platform is designed to coopt nature's universal operating system by harnessing the power of epigenetics, the mechanism for gene control and cell differentiation. We have deciphered the three-dimensional architecture of the human genome and its accompanying regulators, which are organized into distinct and evolutionarily conserved structures called Insulated Genomic Domains, or IGDs. IGDs are the fundamental structural and functional units of gene control and cell differentiation and act as the "control room" of biology. Most diseases are caused by aberrant gene expression rooted in alterations in IGDs. The OMEGA platform has enabled us to systematically identify and validate thousands of novel DNA-sequence-based epigenomic "zip codes" within IGDs. We call these epigenomic targets EpiZips. We rationally design and engineer modular, programmable mRNA-encoded epigenetic medicines, which we call Omega Epigenomic Controllers, or OECs, to target EpiZips for Precision Genomic Control. This enables us to precisely tune genes to a desired level of expression and to control the duration of expression. Through this approach, we believe that the OMEGA platform has broad potential applicability across a range of diseases and conditions. Our pipeline currently consists of programs that span regenerative medicine, multigenic diseases including immunology, oncology, and select monogenic diseases. We have achieved *in vivo* proof-of-concept of our OECs in multiple disease models for various indications, including hepatocellular carcinoma, or HCC, non-small cell lung cancer, or NSCLC, and acute respiratory distress syndrome, or ARDS. We expect to achieve *in vivo* preclinical proof-of-concept for multiple additional programs in . If successful, we plan to initiate investigational new drug application, or IND, enabling studies for multiple programs beginning in .

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

As of December 31, 2020, we had cash and cash equivalents of $23.0 million. In March 2021, we received $125.5 million in gross proceeds from the issuance and sale of our Series C redeemable convertible preferred stock. 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
- operate as a public company.

Impact of COVID-19 on our business

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

To date, we have not experienced material business disruptions as a result of the pandemic. We are following, and plan to continue to follow, recommendations from federal, state and local

governments regarding workplace policies, practices and procedures. In response to the direction from state and local governmental authorities, we have restricted access to our facility to those individuals who must perform critical research and laboratory support activities that must be completed on site, limited the number of such people that can be present at our facility at any one time and required that most of our employees work remotely. In addition, the third-party contract research organizations, or CROs, and contract development and manufacturing organizations, or CDMOs, that we engage have faced in the past and may face in the future disruptions that could affect our ability to initiate and complete preclinical studies, including disruptions in procuring items that are essential for our research and development activities, such as, for example, raw materials used in the manufacture of our product candidates and laboratory supplies for our preclinical studies, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic.

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

Components of our results of operations

Revenue

To date, we have not generated any revenue from any sources, including product sales, and do not expect to generate any revenue from the sale of products for the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval or collaboration or license agreements with third parties, we may generate revenue in the future from product sales, payments from collaboration or license agreements that we may enter into with third parties or any combination thereof. We cannot predict if, when or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidate.

Operating expenses

Research and development expenses

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

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

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

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

General and administrative expenses

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

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

Related party expense, net

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

Other expense, net

Interest expense, net

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

Other expense, net

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

Results of operations

Comparison for the years ended December 31, 2020 and 2019

The following table summarizes the results of our operations for the years ended December 31, 2020 and 2019, together with the changes in those items in thousands of dollars and as a percentage.

	Year ended December 31,		$ Increase / (Decrease)	% Change
	2020	2019		
Operating expenses:				
Research and development	$ 21,063	$ 11,931	$ 9,132	77%
General and administrative	6,236	4,227	2,009	48%
Related party expense, net	1,346	1,181	165	14%
Total operating expenses	28,645	17,339	11,306	65%
Loss from operations	(28,645)	(17,339)	11,306	65%
Other expense, net:				
Interest expense, net	(777)	(595)	182	31%
Other expense, net	(25)	(11)	14	127%
Total other expense, net	(802)	(606)	196	32%
Net loss and comprehensive loss	$(29,447)	$(17,945)	$ 11,502	64%

Research and development expenses

Research and development expenses were $21.0 million and $11.9 million for the years ended December 31, 2020 and 2019, respectively. The increase of $9.1 million was primarily driven by an increase of $7.1 million in laboratory supplies and external research services as a result of our continued research and development efforts in the discovery and preclinical development of our product candidates. Additionally, there was an increase of $1.8 million in employee related expenses due to an increase in headcount in the research and development functions.

General and administrative expenses

General and administrative expenses were $6.2 million and $4.2 million for the years ended December 31, 2020 and 2019, respectively. The increase of $2.0 million was primarily driven by an increase of $0.9 million in employee related expenses due to an increased number of employees in general and administrative functions. The increase was also attributed to an increase of $0.3 million in stock-based compensation due to the equity awards issued to our senior management as well as an increase in the fair value of our common stock during 2020. Additionally, there was an increase of $0.2 million in professional fees, primarily related to the increased legal costs incurred in connection with our ongoing business operations.

Related party expense, net

Related party expense, net was $1.3 million and $1.2 million for the years ended December 31, 2020 and 2019, respectively. The increase of $0.1 million was primarily driven by the $1.0 million of

lease expense and the related costs incurred for our principal office and laboratory space, offset by the $0.7 million sublease income earned and $0.2 million lower expenses incurred for Flagship's management services and other reimbursements.

Interest expense, net

Interest expense, net was $0.8 million and $0.6 million for the years ended December 31, 2020 and 2019, respectively. The increase of $0.2 million was primarily driven by a higher amount of outstanding debt principal throughout 2020 compared to 2019. We initially entered into a loan and security agreement in 2018 for an aggregate principal amount of $8.0 million. In September 2019, we entered into an amendment with the lender to borrow an additional term loan, in an aggregate principal amount of $12.0 million.

Other expense, net

Other expense, net was $25 thousand for the year ended December 31, 2020, which is relatively consistent with other expense, net for the year ended December 31, 2019.

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 and borrowings under our loan and security agreement.

Cash flows

The following table summarizes our sources and uses of cash for the years ended December 31, 2020 and 2019 (in thousands):

	Year ended December 31,	
	2020	2019
Net cash used in operating activities	$ (26,133)	$ (15,679)
Net cash used in investing activities	(1,808)	(885)
Net cash provided by financing activities	48,618	11,985
Net increase (decrease) in cash, cash equivalents and restricted cash	20,677	(4,579)

Operating activities

Net cash used in operating activities totaled $26.1 million in the year ended December 31, 2020 compared to net cash used in operating activities of $15.7 million in the year ended December 31, 2019. The $10.4 million increase in operating cash outflows was primarily attributable to higher net loss recognized year over year, mostly driven by the increased activities in our discovery and preclinical developments.

Investing activities

Net cash used in investing activities totaled $1.8 million in the year ended December 31, 2020 compared to net cash used in investing activities of $0.9 million in the year ended December 31,

2019. The $0.9 million increase in investing cash outflows was primarily attributable to additional capital expenditures resulting from our office move and investment in laboratory equipment as we expanded our discovery and preclinical activities.

Financing activities

Net cash provided by financing activities for the year ended December 31, 2020 consisted primarily of the gross proceeds from the issuance of Series B redeemable convertible preferred stock, Series B Preferred Stock, of $48.6 million. Net cash provided by financing activities for the year ended December 31, 2019 consisted primarily of the gross proceeds from the issuance of Series A redeemable convertible preferred stock of $8.0 million as well as the incremental debt borrowing of $4.0 million.

Loan and security agreement

In March 2018, we entered into the loan and security agreement, Loan Agreement, with Pacific Western Bank, or PWB, under which we borrowed $8.0 million pursuant to Tranche I and Tranche II. In September 2019, we entered into an amendment to the Loan Agreement, or First Amendment, in which PWB made an additional term loan to us in an aggregate principal amount of $12.0 million. The proceeds of the First Amendment was first applied to the repayment in full of all outstanding principal and accrued interest on the outstanding term loan of $8.0 million under Tranche I and Tranche II; the remaining cash proceeds of $4.0 million was used for general working capital and for capital expenditures purposes.

In December 2020, we entered into a further amendment to extend the principal repayment date, and there was no additional proceeds taken under this amendment. The maturity date of the term loan is December 31, 2023, and it is to be repaid beginning on December 31, 2021 in twenty-four equal installments, including interest at a floating annual rate equal to the greater of (i) 0.75% above the prime rate then in effect and (ii) 6.00%, due monthly starting the first month after December 30, 2020. As of December 31, 2020, the interest rate applicable to the term loan was 6.0% and the interest payment on the outstanding term loan was less than $0.1 million per month.

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

Funding requirements

As of December 31, 2020, we had cash and cash equivalents of $23.0 million. In March 2021, we received $125.5 million in gross proceeds from the issuance and sale of our Series C redeemable convertible preferred stock. Without giving effect to the net proceeds from this offering, we do not have sufficient cash and cash equivalents on hand to support current operations for at least one year from the date of issuance of the financial statements appearing elsewhere in this prospectus. As a result, there is substantial doubt about our ability to continue as a going concern for at least one year from the date of issuance of our financial statements included elsewhere in this prospectus. We will need to raise additional capital in this offering and/or otherwise to fund our future operations. However, we cannot guarantee that we will be able to obtain sufficient additional funding in this offering or otherwise or that such funding, if available, will be obtainable on terms satisfactory to us. In the event that we are unable to obtain sufficient additional funding, there can be no assurance that we will be able to continue as a going concern.

We expect that our expenses will increase substantially in connection with our ongoing activities, particularly as we advance preclinical activities and into clinical trials for our product candidates in development. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating and capital expenditures will depend largely on:

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

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements . We have based this estimate on assumptions that may prove to be incorrect, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources. 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.

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 such payments are not known.

We have also entered into license agreements with Flagship Pioneering Innovations V, Inc., Whitehead Institute for Biomedical Research, and Acuitas Therapeutics, Inc., 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 $12.0 million under the Loan Agreement, as amended. Pursuant to the terms of the Loan Agreement, as amended, interest payment on the outstanding term loan is less than $0.1 million per month, and we are obligated to repay $0.5 million of principal payment per month, starting December 31, 2021 until the maturity date of December 31, 2023.

In July 2020, we entered into a Shared Space Agreement with an affiliate of Flagship for our principal office and laboratory space. The Shared Space Arrangement commenced on August 1, 2020 and continues through July 31, 2022 with two options to extend the term for a period of 24 months each. Our lease payments for the remainder of the lease term will be approximately $0.2 million per month.

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

Critical accounting policies and estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting

principles generally accepted in the U.S., or GAAP. The preparation of these 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 Financial Statements appearing at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued research and development expenses

As part of the process of preparing our 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 financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to vendors in connection with preclinical development activities, CROs in connection with research activities, and CDMOs in connection with the production of research materials.

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

Stock-based compensation

We measure our stock option awards based on the fair value on the date of the grant using the Black-Scholes option-pricing model. The fair value of our stock option awards is estimated using the following inputs: (1) fair value of our common stock, (2) assumptions we make for the expected volatility of our common stock, (3) the expected term of our stock option wards, (4) the risk-free interest

rate for a period that approximates the expected term of our stock option awards, and (5) our expected dividend yield, if any. The fair value of our common stock is used to determine the fair value of restricted stock awards.

Compensation expense for our stock-based compensation awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We recognize forfeitures as they occur. We use the straight-line method to record the expense of awards with service-based vesting conditions.

Determination of the fair value of common stock

As there is no public market for our common stock, the estimated fair value of our common stock is determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believes are relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations are performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations are prepared using either an option pricing method, or OPM, or a hybrid method of the probability-weighted expected return method, or PWERM, both of which use market approaches to estimate our enterprise value. The OPM treats common stock and redeemable convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeds the value of the redeemable convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

The hybrid method is a probability-weighted expected return method, or PWERM, by which the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

These independent third-party valuations were performed at various dates, which resulted in estimated valuations of our common stock by our board of directors of $0.16 per share as of June 30, 2019, $0.68 per share as of July 31, 2020, $1.50 per share as of March 18, 2021, and $1.73 per share as of April 30, 2021. In addition to considering the results of these third-party valuations, our board of directors considers various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the price at which we sold shares of redeemable convertible preferred stock and the superior rights and preferences of the redeemable convertible preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and our business strategy and the material risks related to our business and industry;

- external market conditions affecting the biopharmaceutical industry and the material risks related to our business and industry, and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our redeemable convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or a sale of our company in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in our industry.

The assumptions underlying these valuations represent management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we use significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Following the closing of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

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 Financial Statements appearing at the end of this prospectus, such standards will not have a material impact on our financial statements or do not otherwise apply to our current operations.

Quantitative and qualitative disclosures about market risks

We are exposed to certain market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of changes in interest rates. We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we do contract with vendors that are located outside of the United States and may be subject to fluctuations in foreign currency rates. We may enter into additional contracts with vendors located outside of the United States in the future, which may increase our foreign currency exchange risk.

Interest rate risk

As of December 31, 2020, we had cash and cash equivalents of $23.0 million. Our exposure to interest rate sensitivity is impacted by changes in the general level of U.S. interest rates. Our surplus cash has been invested in interest-bearing savings account from time to time, and we have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate 10% change in interest rates would have a material effect on the fair market value of our portfolio, and therefore, we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

As of December 31, 2020, we had borrowings of $12.0 million outstanding under our loan and security agreement with Pacific Western Bank. Outstanding borrowings bear interest at a variable rate

equal to the greater of (i) 0.75% above the bank's prime rate then in effect or (ii) 6.00%. An immediate 10% change in the variable interest rate would not have had a material impact on our debt-related obligations, financial position or results of operations.

Emerging growth 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. For additional information, see "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

BUSINESS

Overview

At Omega Therapeutics, our goal is to pioneer a new class of DNA-sequence-targeting, mRNA-encoded therapeutics to fundamentally transform human medicine in the service of patients. Our pioneering OMEGA Epigenomic Programming platform is designed to coopt nature's universal operating system by harnessing the power of epigenetics, the mechanism for gene control and cell differentiation. We have deciphered the three-dimensional architecture of the human genome and its accompanying regulators, which are organized into distinct and evolutionarily conserved structures called Insulated Genomic Domains, or IGDs. IGDs are the fundamental structural and functional units of gene control and cell differentiation and act as the "control room" of biology. Most diseases are caused by aberrant gene expression rooted in alterations in IGDs. The OMEGA platform has enabled us to systematically identify and validate thousands of novel DNA-sequence-based epigenomic "zip codes" within IGDs. We call these epigenomic targets EpiZips. We rationally design and engineer modular, programmable mRNA-encoded epigenetic medicines, which we call Omega Epigenomic Controllers, or OECs, to target EpiZips for Precision Genomic Control. This enables us to precisely tune genes to a desired level of expression and to control the duration of expression. Through this approach, we believe that the OMEGA platform has broad potential applicability across a range of diseases and conditions. Our pipeline currently consists of programs that span regenerative medicine, multigenic diseases including immunology, oncology, and select monogenic diseases. We have achieved *in vivo* proof-of-concept of our OECs in multiple disease models for various indications, including hepatocellular carcinoma, or HCC, non-small cell lung cancer, or NSCLC, and acute respiratory distress syndrome, or ARDS. We expect to achieve *in vivo* preclinical proof-of-concept for multiple additional programs in . If successful, we plan to initiate investigational new drug application, or IND, enabling studies for multiple programs beginning in .

The OMEGA platform consists of four pillars:

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

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

We believe that the OMEGA platform has the following advantages:

- Pioneering IGDs and EpiZips as novel therapeutic targets.

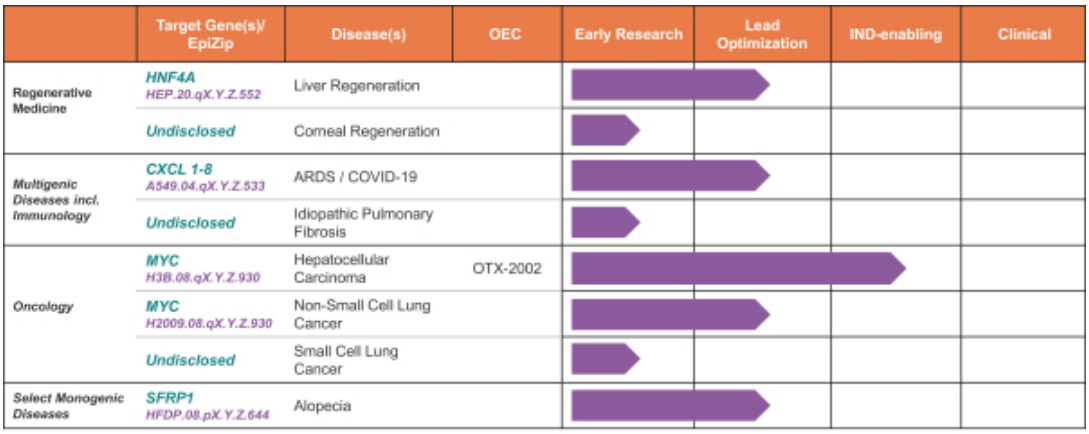
- Precision genomic control with tunable and durable effect with the potential to re-dose.
- Single and/or multiple gene control with a single therapeutic.
- Ability to multiplex within or across IGDs for synergistic effect.
- No changes in nucleic acid sequences.
- Ability to accelerate numerous programs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

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

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

Our Pipeline

Our pipeline consists of the following programs:



Regenerative Medicine

We are developing OEC candidates to up-regulate the expression of HNF4a, a transcriptional master regulator, as a potential way to restore liver-cell function in patients suffering from severe liver dysfunction. In preclinical studies, we have observed durable increases in HNF4a and significant improvements in liver histology *in vivo*.

We are also developing OEC candidates to control the expression of genes that have been strongly linked to cell-growth inhibition in patients with diabetes and other conditions to restore the capacity for corneal regeneration.

Multigenic Diseases Including Immunology

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

We are also developing OEC candidates to control expression of genes implicated in patients with idiopathic pulmonary fibrosis, or IPF, to halt or reverse disease progression and improve disease outcomes.

Oncology

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

We are also developing OEC candidates for the treatment of NSCLC and small cell lung cancer, or SCLC. In preclinical studies in NSCLC xenografts in a mouse subcutaneous tumor model, we observed a 63% inhibition in tumor growth following administration of an OEC candidate compared to control.

Select Monogenic Diseases

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

Intellectual Property and Manufacturing Capabilities

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

Our History and Team

Flagship Pioneering, or Flagship, founded Omega Therapeutics in 2017 as VL42, Inc. The Flagship origination team, led by Dr. David Berry, working together with Dr. Noubar Afeyan, CEO of Flagship, set out to more fully understand epigenetic regulation and non-genetically alter it through experimentation at Flagship Labs. VL42 was based on an exploration posing the question: “What if epigenetics worked through a universal operating system and what if we could interrogate that system and therapeutically intervene?” This exploration yielded critical insights on epigenomics, including intervention points and the use of controllers as a means to control the expression of one or more coordinated genes. We created Omega Therapeutics to develop a platform to design and make a new

category of medicines, one that can harness the potential of IGDs and epigenetic control, and lead to the treatment of important diseases with high unmet medical needs. As part of creating Omega Therapeutics, Flagship complemented its own epigenomic patent estate licensed to Omega Therapeutics with exclusive licenses to patent estates in epigenetics from the Whitehead Institute at the Massachusetts Institute of Technology (Dr. Rudolf Jaenisch's lab and Dr. Richard Young's Lab).

We have built a world-class team of talented and highly experienced leaders to set and execute our strategy in fulfillment of our vision of pioneering the development of a new class of epigenetic medicines. Our leadership team has more than 100 years of combined experience in the pharmaceutical and biotechnology industry, has been involved in filing more than 30 INDs and 20 submissions for product approval, and has launched more than 30 pharmaceutical products globally. Mahesh Karande, our Chief Executive Officer, has a track record of leading biopharmaceutical businesses across the discovery, preclinical- and clinical-development, commercialization, and product-life-cycle-management stages to drive portfolio value and company growth. He previously served as President and Chief Executive Officer of Macrolide Pharmaceuticals, led Novartis Oncology's solid tumor franchise in the United States, and held several senior leadership roles at Novartis across the globe. Our Chief Scientific Officer, Thomas McCauley, Ph.D., has over 21 years of experience in the biopharmaceutical industry building and leading research-and-development organizations at the forefront of advanced genetic therapies across therapeutic areas and has made key contributions to the development, global registration, approval and life-cycle management of more than ten marketed products. He previously served as the Chief Scientific Officer of Translate Bio and Macrolide Pharmaceuticals. Our Chief Financial Officer, Roger Sawhney, M.D., has over 25 years of financial and strategic expertise, ranging from global investments in the healthcare sector to business and strategy development in the biopharmaceutical industry. He previously served as the Head of Global Corporate Strategy for Novartis AG. We have also assembled a scientific advisory board of leaders with deep expertise in genomics, epigenetics, and chromatin biology, as well as target biology and clinical development experience.

Our culture is inspired by our values and behaviors and is guided by our overarching ethos: Ambitious, yet humble. Our team has the ambition to succeed in our pioneering journey, however, we are grounded in humility given the enormous responsibility of eventually treating patients with our transformative medicines. We are blazing a **TRAIL** with our values of **T**rust, **R**esilience, **A**uthenticity, **I**nnovation and **L**eadership, which reflect this ethos and are hallmarks of our high-performance culture.

Since inception, we have raised approximately $200 million from Flagship as well as major mutual funds, healthcare-dedicated funds, and other leading investors.

Our Strategy

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

Our strategy includes:

- ***Strategically invest in and advance the OMEGA platform***. Our scientific and technical expertise and expansive intellectual property estate have enabled us to develop our industry-leading, pioneering OMEGA platform. We plan to continue to invest in expanding our knowledge of IGD biology and epigenetics in order to identify new DNA-sequence-based epigenomic targets, the EpiZips, further our capacity to innovate and engineer OECs, expand our technologies, broaden our delivery capabilities, and enhance our institutionalized knowledge to further solidify our position as a leading digital and data-driven epigenetic

medicines company. We plan to build additional computational, big-data, and advanced-analytic capabilities to maintain our leadership position.

- ***Establish OECs as a new class of transformative medicine.*** Through the breadth of our research-and-development activities and the pursuit of high-value biological targets, we seek to demonstrate the unprecedented therapeutic potential of our OECs and to expand our repertoire of OECs that can be used for therapeutic applications. We have achieved *in vivo* proof-of-concept of our OECs in multiple disease models for various indications, including HCC, NSCLC, and ARDS. We expect to achieve *in vivo* preclinical proof-of-concept for multiple additional programs in . If successful, we plan to initiate IND-enabling studies for multiple programs beginning in .
- ***Expand our pipeline through internal and collaboration efforts.*** We believe the OMEGA platform can be used to create therapeutics to treat a broad array of human diseases by regulating the expression of single or multiple genes. Internally, we intend to focus our development and commercialization efforts in areas of high unmet need with well-defined and circumscribed patient populations. At the same time, we plan to seek collaborations or co-development programs to mitigate development risk or gain access to novel delivery technologies.
- ***Build a fully integrated digitalized biopharmaceutical company.*** Our intent is to develop a world-class biopharmaceutical company by leveraging our innate and differentiated platform attributes and digitalized end-to-end capabilities across research, discovery, preclinical and clinical development, manufacturing, and commercial operations. We believe the integrated and modular nature of the OMEGA platform enables iterative learnings and insights for efficient, evidence-based decision making to optimize the engineering, development, and selection of our OEC candidates.
- ***Curate world-class talent and culture.*** Our culture is guided by our overarching ethos: Ambitious, yet humble. Our unparalleled motivation to transform human medicine through our pioneering work is combined with our underlying sense of humility, which is essential for keeping patients front and center. Given the pioneering nature of our business, identifying, nurturing, developing, and retaining leading talent is a critical element of our strategy.

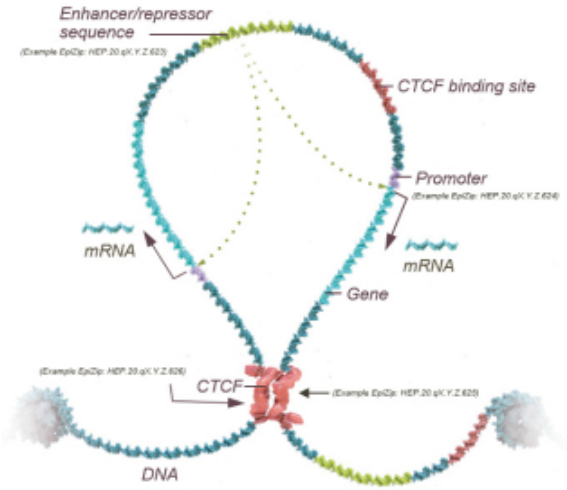
Background of Insulated Genomic Domains (IGDs)

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

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

players in the formation and maintenance of the IGD structure. Cohesin is the motor that extrudes and enlarges the IGD loop, while CTCF blocks cohesin from further extrusion and acts as an anchor, thereby enforcing boundaries between IGDs.

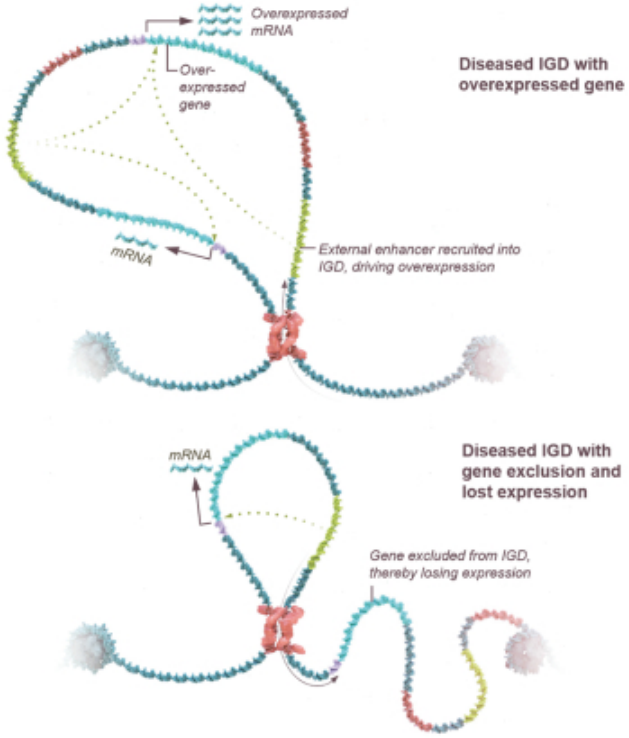
Graphical Representation of an IGD



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

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

Illustrative Examples of Structurally Dysregulated IGDs



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

OMEGA Epigenomic Programming Platform

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

The OMEGA platform consists of four pillars.

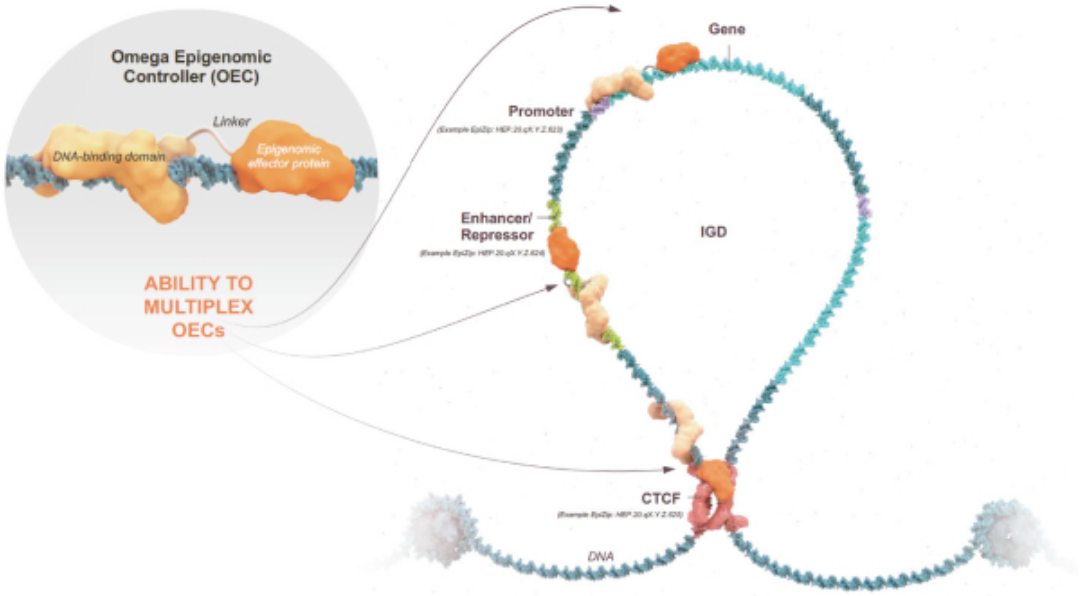
1. Proprietary Database of IGDs and EpiZips

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

2. Modular Programmable Epigenetic Medicines Encoded as mRNA (OECs)

We have created a modular basis for efficient and intelligent design of programmable epigenetic medicines, the OECs. These engineered and modular mRNA-encoded medicines allow us to regulate multiple genes with exquisite specificity, controllable tuning, and duration of effect. Our OECs are fusion proteins comprised of two components—a programmable 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, 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 OECs, including programming DNA-binding domains and selecting optimal epigenomic effector proteins. These computational tools allow us to efficiently generate numerous potential OECs and increases our ability to engineer OECs to treat a particular target.

Omega Epigenomic Controller



We are currently developing proprietary zinc-finger-like proteins and other DNA-binding domains. For epigenetic effectors, we have generated and continue to build a library consisting of more than 100 single- and multi-functional epigenetic 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 OECs 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 OECs to modulate them in potentially as little as a few weeks.

3. Engineered, Customized Drug Delivery

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

4. Industry-Leading Expertise

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

Computational Foundation

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

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

We have a highly skilled computational team with deep expertise and broad experience, supporting the OMEGA platform. This team develops the tools, capabilities, and specialized methods

needed to address the complexity of IGD biology, design, and delivery of our OECs, and integration of a computation- and data-first philosophy company wide. We are continually growing and evolving our computational team and capabilities to drive innovation in the discovery and development of programmable epigenetic medicines, manufacturing, and our digital foundation.

Advantages of the OMEGA Platform

Epigenomic programming is a transformative new approach to biologically engineer programmable epigenetic medicines to treat disease. We believe that our mRNA-encoded OECs' ability to precisely target and provide tunable and durable effects has the potential to treat a wide range of diseases and has the following advantages:

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

Our Development Programs

We are currently advancing our development programs in regenerative medicine, multigenic diseases including immunology, oncology, and select monogenic diseases. We have achieved *in vivo*

proof-of-concept of our OECs in multiple disease models for various indications, including HCC, NSCLC, and ARDS. We expect to achieve *in vivo* preclinical proof-of-concept for multiple additional programs in . If successful, we plan to initiate IND-enabling studies for multiple programs beginning in .

Regenerative Medicine

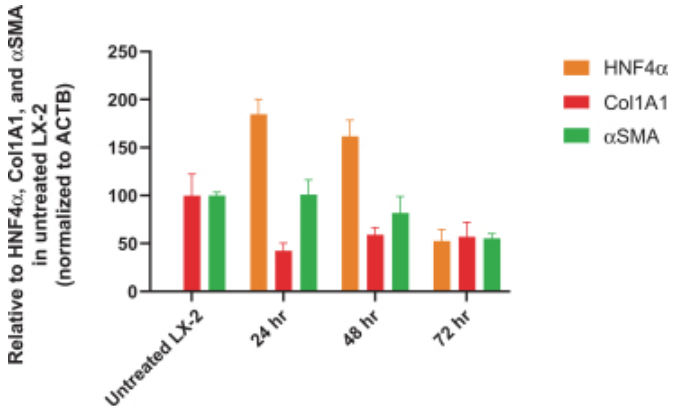
Liver Regeneration

We are developing OEC candidates designed to increase expression of HNF4a, a transcriptional master regulator, as a potential way to restore liver-cell function in patients with severe liver dysfunction. HNF4a controls development, differentiation, and homeostasis of hepatocytes and other cell types in the liver by controlling the expression of proteins, such as bilirubin, albumin, and metabolic enzymes, that are essential for normal liver function. In chronic liver disease, HNF4a is down-regulated, which contributes to the pathology of liver failure. Studies have shown that increased expression of HNF4a in even a modest fraction of hepatocytes can restore healthy liver function.

In 2017, chronic liver disease that is secondary to cirrhosis was the 11th leading cause of death in the United States, accounting for over 40,000 deaths. Depending on the etiology of disease, treatment options may include corticosteroids, antivirals or other drugs, with the final option being liver transplantation. In 2018, in the United States, there were more than 14,000 people on the liver transplant waiting list and approximately 25% died before receiving a transplant.

In preclinical studies in primary healthy human hepatocytes, treatment with our OEC candidate induced a durable increase in HNF4a for up to ten days, which we believe may be sufficient to return hepatocytes to a functional state and restore liver function in CLD and ESLD patients. We also observed decreases in collagen 1A1, or Col1A1, and alpha smooth muscle actin, or aSMA, both biomarkers of liver injury and fibrosis, as shown in the graph below. At 72 hours, we observed reductions of approximately 50% in both Col1A1 and aSMA relative to untreated cells. These data showed a reduction in expression of these downstream biomarkers of liver damage in response to the up-regulation of HNF4a and support the proposed therapeutic mechanism of action of our OEC candidate.

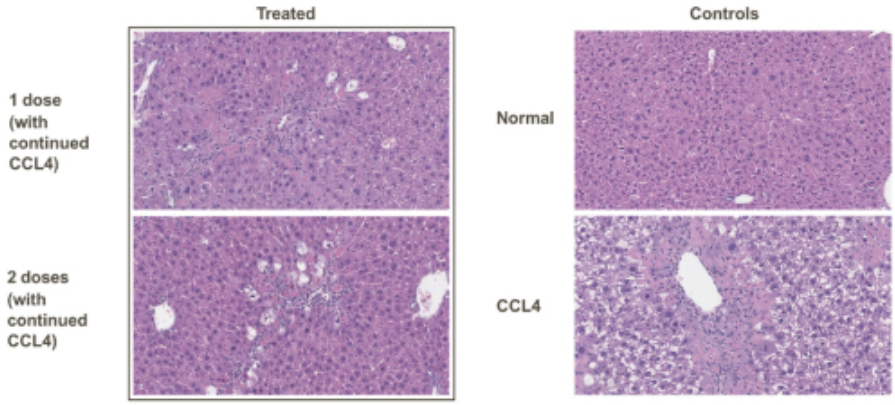
OEC candidate reduced biomarkers of liver damage (*in vitro*)



As shown in the images below, in an *in vivo* preclinical mouse liver fibrosis model, carbon tetrachloride treatment was used to induce hepatocellular degeneration (labeled CCl_4 in the images

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

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



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

Corneal Regeneration

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

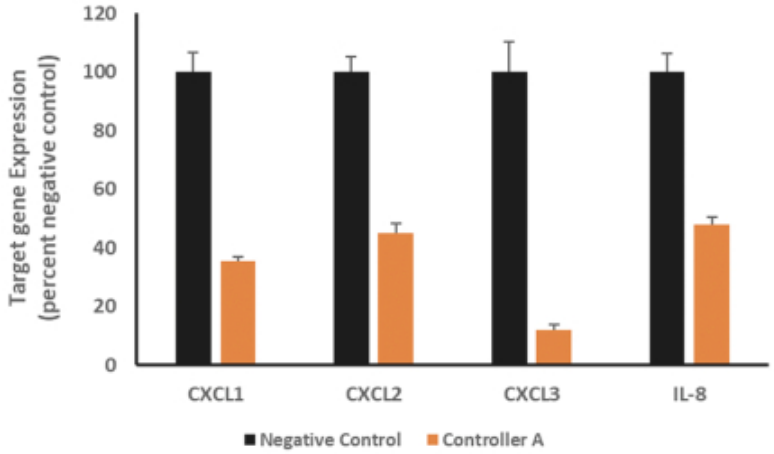
Multigenic Diseases Including Immunology

Acute Respiratory Distress Syndrome

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

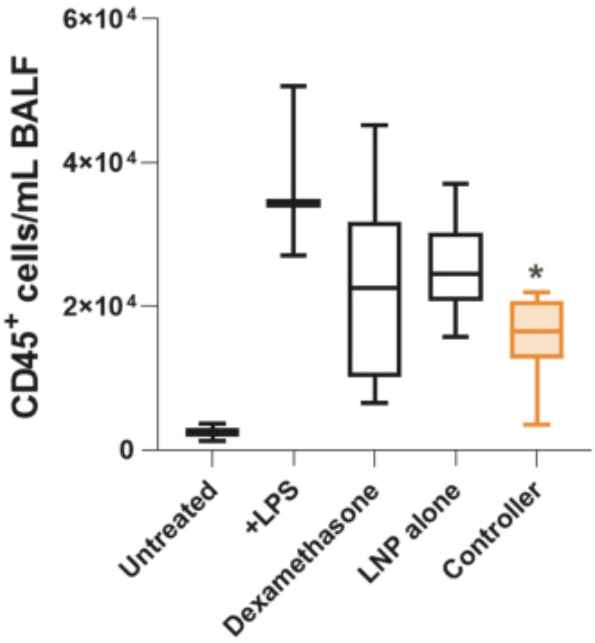
In a preclinical study of an OEC candidate (Controller A in the graph below) in human monocytes, at 24 hours post-dosing we observed a 65% decrease in gene expression of CXCL1, a 55% decrease in gene expression of CXCL2, an 88% decrease in gene expression of CXCL3, and a 52% decrease in gene expression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

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



In a preclinical study in an animal model of ARDS, we observed a significant decrease in neutrophil infiltration in lungs treated with an OEC candidate. Animals were administered 3 mg/kg of the OEC candidate (labeled Controller in the graph below) two hours prior and eight hours after lipopolysaccharide insult to induce inflammation or 10 mg/kg dexamethasone daily as a positive control. As shown in the graph below, we observed a 56% decrease in neutrophils infiltration in broncho-alveolar lavage fluid (labeled BALF in the graph below) in mice 72 hours after treatment with the OEC candidate relative to disease control, a measure of the severity of the inflammatory response.

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



**** p<0.05 compared to +LPS***

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

Idiopathic Pulmonary Fibrosis

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

Oncology

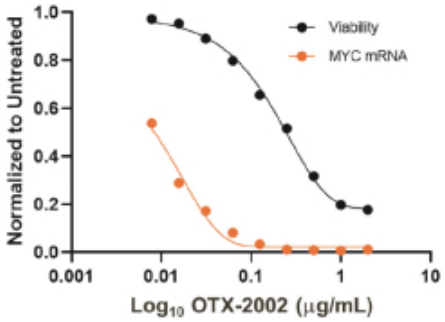
Hepatocellular Carcinoma

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

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

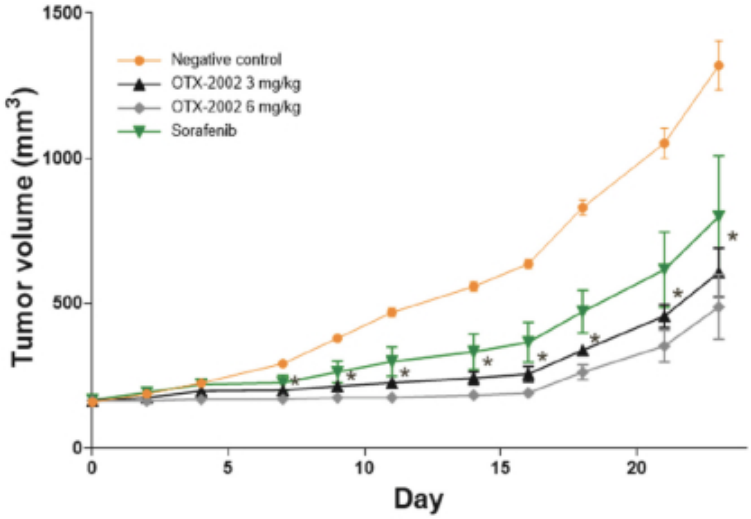
In a preclinical study of OTX-2002 in various HCC cell lines, OTX-2002 down-regulated c-Myc and we observed loss of cellular viability across targeted HCC subtypes with effects observed for 15 days. As shown in the graph below, the EC_{50}, which measures the concentration of a drug that provides a 50%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



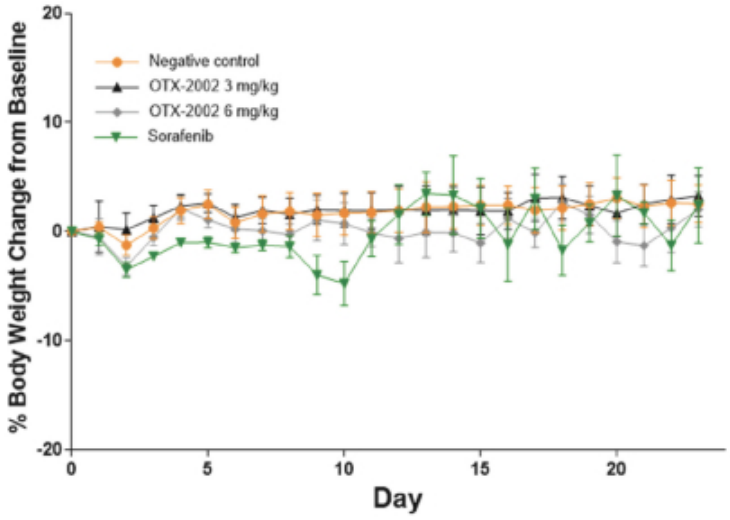
OTX-2002 delivered via formulated LNPs *in vivo* decreased tumor burden in mice containing human HCC xenografts. In this preclinical study, we administered OTX-2002 in a mouse subcutaneous tumor model at doses of 3 and 6 mg/kg every five days and sorafenib at 50 mg/kg daily. As shown in the graph below, treatment with OTX-2002 at 3 mg/kg was associated with a statistically significant reduction in tumor size following two administrations, resulting in a 54% inhibition of tumor growth by Day 23 compared to negative control. Similarly, treatment with a 6 mg/kg dose of OTX-2002 was associated with a statistically significant reduction in tumor size following two administrations, resulting in 63% lower tumor volume at Day 23 compared to negative control. Treatment with OTX-2002 at 3 mg/kg was equivalent to treatment with sorafenib. Mice treated with OTX-2002 did not experience a significant decrease in body weight. Mice treated with sorafenib experienced an initial drop in body weight with a later gain in overall body weight potentially due to an increase in tumor mass. These data indicate that treatment with OTX-2002 was well-tolerated in this study.

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



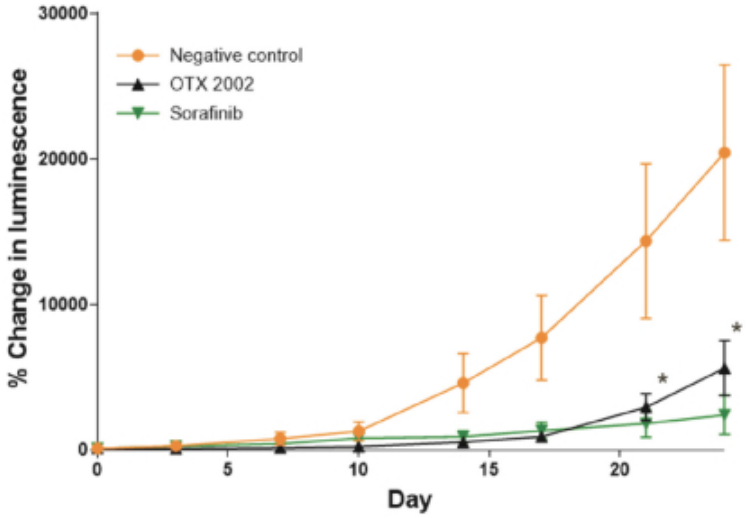
**** p<0.05 compared to negative control***

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



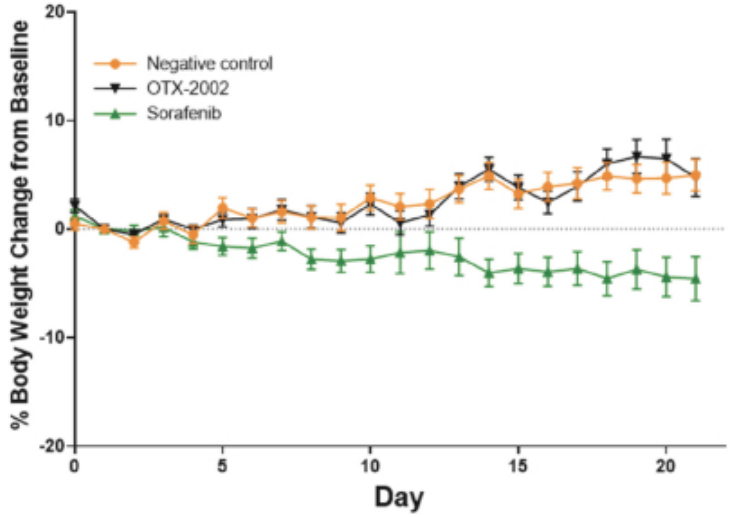
In addition, we observed an equivalent effect on tumor growth from OTX-2002 in mice containing human HCC xenografts compared to sorafenib. Mice were administered 3 mg/kg of OTX-2002 every five days or 50 mg/kg of sorafenib once daily. Tumor growth was measured using bioluminescent imaging. As shown in the graph below, treatment with OTX-2002 resulted in a comparable reduction in luminescence as treatment with sorafenib. Mice treated with OTX-2002 did not experience a significant decrease in body weight. Mice treated with sorafenib experienced a sustained loss in body weight. These data indicate that treatment with OTX-2002 was well-tolerated in this study.

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



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

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



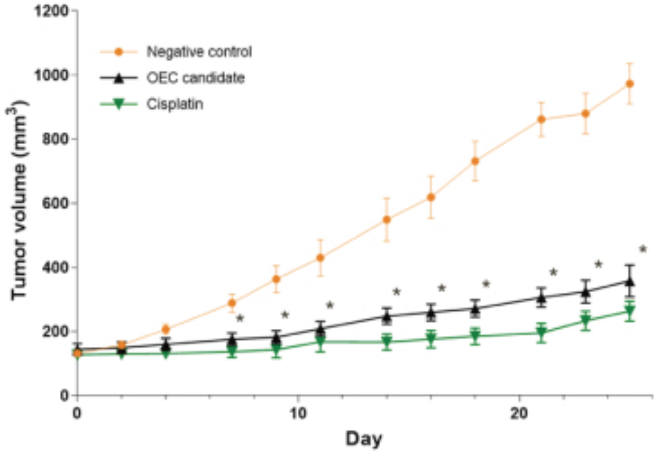
We are conducting additional preclinical studies in subcutaneous and orthotopic liver tumor models and have initiated *in vivo* safety studies.

Non-Small Cell Lung Cancer

We are evaluating additional epigenetic control points for c-Myc down-regulation in NSCLC. Approximately 50% of NSCLC tumors overexpress c-Myc. We are developing an OEC candidate to down-regulate c-Myc and reduce this overexpression. NSCLC is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses, which was approximately 192,200 new cases in the United States in 2020. The five-year survival rate for NSCLC is 24%. Depending on the stage of disease at diagnosis, current treatment options include therapies such as surgical resection, photodynamic therapy (PDT), laser therapy, or brachytherapy, chemotherapy, radiation therapy, targeted therapies (e.g., TKIs) and immunotherapy in combination with other therapies.

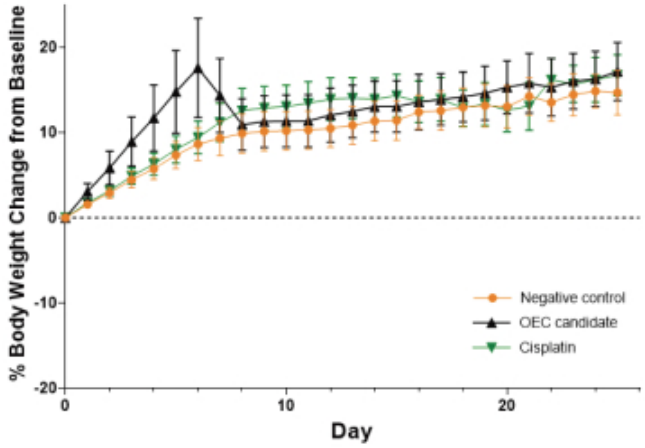
We have identified OEC candidates that have shown activity against a range of NSCLC cell lines *in vitro* in preclinical studies, showing down-regulation of c-Myc with concomitant loss of cellular viability. We also conducted a preclinical study in NSCLC xenografts in a mouse subcutaneous tumor model.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

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



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

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



Small Cell Lung Cancer

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

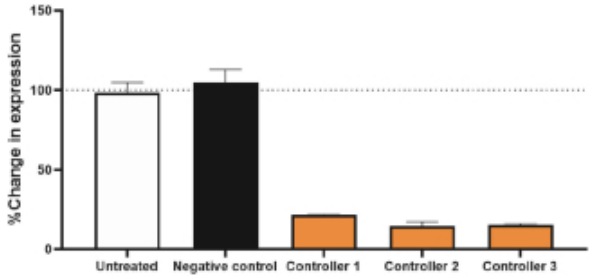
Select Monogenic Diseases

Alopecia

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

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

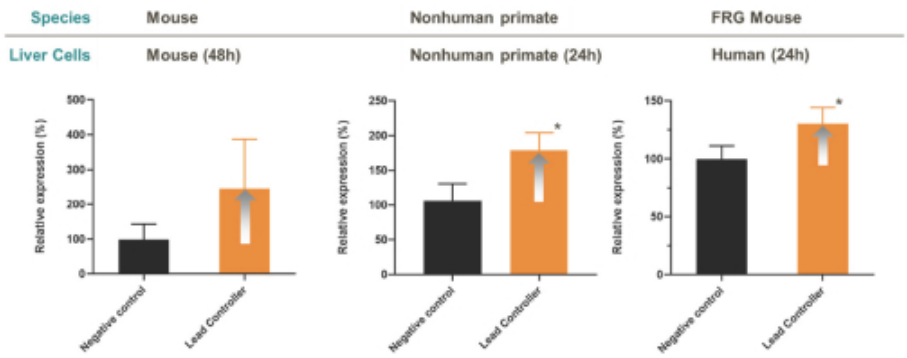
Decrease in SFRP1 mRNA expression in human papilla cells (*in vitro*)



Translational Data

A critical element for the clinical translation of our OEC candidates is our ability to design OEC candidates that can target IGDs and tune gene expression across species. In preclinical studies, we evaluated changes in HNF4a expression in non-human primates and in human liver tissue engrafted and grown in a mouse (labeled FRG Mouse in the graph below) treated with our OEC candidate and in healthy mice treated with an OEC candidate designed to target the homologous murine target sequence. As shown in the graph below, we observed therapeutically relevant up-regulation of HNF4a compared to control, with results showing a 246% increase in mice, 68% increase in non-human primates, and 31% increase in the FRG mouse. We believe that this translational fidelity of our mechanism of action supports our continued development of our OEC candidates and programs.

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

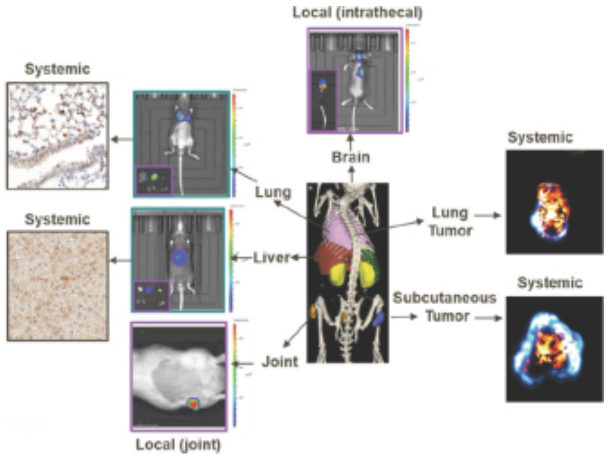


**** p<0.05 compared to negative control***

Delivery Data

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

Delivery Omega Epigenomic Controllers



Manufacturing

We view the development of manufacturing capability, capacity, and control as critical to our overall success and specifically to our ability to meet our development timelines, contain operational

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

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

For our delivery technology, initially, we have engaged with a third-party provider with extensive LNP intellectual property that we believe will allow us freedom to operate and provide significant formulation and manufacturing expertise that will facilitate the transfer of processes for LNP formulation of mRNA under cGMP standards to CDMOs. We have also engaged with a highly experienced CDMO that will manufacture and release our LNP-formulated mRNA for our first set of product candidates.

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

Competition

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

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

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

While we are not aware of other companies developing epigenomic controllers, we expect to compete with companies developing technologies that focus on gene-expression control using various technologies, such as CRISPR gene editing, gene therapies, non-coding RNA therapeutics, and small-molecule epigenetics. These companies include: Alnylam Pharmaceuticals, Inc., Beam Therapeutics Inc., Biogen Inc., Constellation Pharmaceuticals, Inc., CRISPR Therapeutics AG, Editas Medicine Inc., Epizyme Inc., Ionis Pharmaceuticals, Inc., Intellia Therapeutics, Inc., Janssen Pharmaceutical Companies of Johnson & Johnson, Pfizer Inc., and Sangamo Therapeutics Inc. These technologies, along with other modalities, such as small molecules and biologics, may be used to develop therapeutic candidates that would compete against our current, and potentially future, product candidates. In addition, we expect any OECs we develop to compete with established therapeutic treatments, if any, in their target indication.

Intellectual Property

We believe our intellectual property estate is a strategic asset that has the potential to provide us with a competitive advantage. We strive to protect our proprietary technology, inventions and improvements that are commercially important to our business, including pursuing, maintaining, defending, and asserting patent rights, whether developed internally or licensed from third parties. Our policy and practice is to protect our proprietary position by, various methods including, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology (e.g., OMEGA platform, OECs, delivery and manufacturing technology), inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates. We continue to innovate and pursue in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of epigenetic medicine. We additionally rely on data exclusivity, market exclusivity and patent term extensions when available and plan to seek and rely on regulatory protection afforded through orphan drug designations for our therapeutic products. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

Our wholly owned and in-licensed patent portfolio cover various aspects of the OMEGA platform, including, manufacturing, delivery, OECs and our therapeutic programs. Our patent portfolio also covers our product candidates that are in development. As of April 30, 2021, our patent portfolio consists of 25 patent families, including 21 pending U.S. patent applications (including provisional applications), 17 pending foreign patent applications in Europe, Australia, Canada, China, Hong Kong, Mexico, and Japan and nine owned or in-licensed Patent Cooperation Treaty applications, or PCT applications, that have not entered national phase. Any US or foreign patents issuing from the patent applications in our patent portfolio will expire between 2035 and 2042, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance,

renewal, annuity and other governmental fees. Our objective is to continue to expand our patent portfolio to protect our proprietary technology (including the OMEGA platform, OECs, delivery and manufacturing technology), inventions, improvements and current and future product candidates.

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 applications directed to the OMEGA platform and other technologies developed internally and in-licensed exclusively or co-exclusively from the Whitehead Institute for Biomedical Research and Flagship Pioneering. Our platform intellectual property portfolio relates to compositions and methods for the identification, interrogation, and modulation of IGDs. Specifically, these patent applications relate to, for example:

- Gene activating and inhibiting OECs;
- CTCF binding sites, promoter & enhancer targeting DNA binding compositions;
- RNA binding proteins and effector compositions;
- Methods for upregulating or downregulating gene expression by targeting IGDs at CTCF binding sites, promoters and enhancers;
- Computational methods for identifying and interrogating IGDs;
- Methods and compositions for modulating single or multiple genes in IGDs;
- Delivery compositions and methods of use; and
- Therapeutic compositions and methods of treatment.

Our platform technologies, and our intellectual property protection related thereto, are broadly applicable to our product candidates.

Disease-related intellectual property

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

HNF4a

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

MYC

Our OTX-2002 program targets the c-Myc family oncogene. We have developed OECs that downregulate c-Myc for the treatment of HCC. We also have a program designed to reduce the expression of c-Myc to treat NSCLC. Our MYC patent portfolio currently includes two U.S. provisional patent applications, one U.S. non-provisional patent application and two foreign patent applications in Europe and Hong Kong related to OEC compositions of matter, methods of treating c-Myc related cancers and methods of modulating c-Myc expression. We expect patents issuing from the pending patent applications in this portfolio to expire between 2037 and 2041, excluding any patent term adjustments or extensions. In addition, we have non-exclusively in-licensed patent applications from Acuitas Therapeutics, Inc., or Acuitas, that cover the LNP delivery formulation and lipids utilized for OTX-2002.

CXCL1, 2, 3, and IL-8

We are developing OEC candidates to reduce expression of the CXCL1, 2, 3, and IL-8 gene cluster. The program is designed to reduce expression of chemokines that are over-expressed in a broad range of inflammatory disorders, including rheumatoid arthritis, gout, neutrophilic asthma, and ARDS. We are currently developing OEC candidates that target a key CTCF binding site of the CXCL 1-3/IL-8 IGD. Our CXCL 1-3/IL-8 patent portfolio currently includes one U.S. provisional patent application relating to OEC compositions that target the CXCL 1-3/IL-8 IGD, and methods of treating inflammatory disorders, including rheumatoid arthritis, gout, neutrophilic asthma, and ARDS. We expect patents issuing from the pending patent applications in this portfolio to expire in 2041, excluding any patent term adjustments or extensions.

In addition to our disease programs listed above, we also have patent applications relating to novel OEC compositions and their use for treating additional disorders that would benefit from upregulation or downregulation of gene expression, including other cancers, inflammatory disorders, neurological and metabolic disorders. We expect the patents issuing from patent applications in this portion of our portfolio to expire between 2040 and 2042, without taking into account any patent term adjustments or extensions we may obtain.

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 Pioneering Innovations V, Inc., or Flagship, pursuant to which (i) we irrevocably and unconditionally assigned to Flagship all of our right, title and interest in and to certain foundational intellectual property conceived prior to our launch, 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 our launch, and (iii) as a result of activities conducted pursuant to that certain managerial agreement with Flagship Management, Managerial Agreement, or other participation of Flagship Management in our affairs, but excluding Foundational IP. Foundational IP is directed, among other things, to methods and compositions to modulate gene expression by targeting IGDs, and we utilize the rights granted by Flagship under the Flagship Agreement in our OMEGA platform and related therapeutic product candidates. The license granted to Foundational IP is contingent upon our compliance with our obligations under the Flagship Agreement. Under the Flagship Agreement, we also granted Flagship a non-exclusive, worldwide, royalty-free, fully paid, sublicensable license 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.

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. 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.

Exclusive and Co-Exclusive License Agreements with WIBR

In May 2019, we and the Whitehead Institute for Biomedical Research, or 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 Exclusive Agreement 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 is required to grant non-exclusive rights to the licensed patents to said third party if certain inventions arise under the SRA, or SRA inventions, and patent applications are filed on such SRA inventions, and such patent applications would be dominated by the licensed patents. We are excluded from asserting any licensed patents 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 low double digit, 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.

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 a sub single digit percentage royalties on net sales of licensed products and low single digit percentage royalties on licensed services income until, on a country-by-country basis, the expiration or abandonment of the patent rights. We are entitled to

certain customary reductions and offsets on these royalties with respect to a licensed product in a given country. If we sublicense our rights to develop or commercialize a licensed product under the WIBR Co-Exclusive Agreement, WIBR is entitled to a mid-five figure yearly payment for each such sublicense agreement that grants a sublicensee the right under the licensed patents.

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 lipid nanoparticles, or 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 patents and know-how related to LNP technology, or Acuitas LNP Technology, with respect to two specified targets (e.g., OEC constructs), or Reserved Targets, to develop and commercialize one or more therapeutic products including mRNAs that encode the Reserved Targets. For each option and Reserved Target, we are obligated to pay an annual technology access fee and target reservation and maintenance fees collectively in the low-mid six figures until such Reserved Targets is removed from the Reserved Target list or until we exercise an option with respect to such Reserved Target. On exercise of the first option, we are required to pay a $1.5 million option exercise fee after execution of the first non-exclusive license. On exercise of the second option, we are required to pay a $1.75 million option exercise fee after execution of the second non-exclusive license.

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.

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. 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 gene modulating therapeutics and Acuitas's LNPs. We paid Acuitas an option exercise fee of $1.5 million. 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 and regulatory milestone payments of up to $18.0 million in the aggregate. With respect to the sale of each licensed product by us, our affiliates or our sublicensees, Acuitas is entitled to receive low single digit percentage royalties on net sales of the licensed product in a given country until the last to occur, in such country, of (i) the expiration or abandonment of all licensed patent rights covering the licensed product, (ii) expiration of any regulatory exclusivity for the licensed product, or (iii) ten years from the first commercial sale of the licensed product, or Royalty Term. We are entitled to certain royalty reductions and offsets with respect to each licensed product in a given country if no licensed patents cover the licensed product or if we are required to obtain rights to third party patents that relate to LNP technology. Unless earlier terminated, the Acuitas License Agreement will remain in effect until the expiration of the last-to-expire Royalty Term. Either party may terminate the Acuitas License Agreement for an uncured material breach of the other party upon the other party's bankruptcy or a similar event. We may terminate the Acuitas License Agreement at our convenience following written notice to Acuitas.

Government Regulation

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

U.S. biological products development process

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

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, and pre-clinical 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 investigational new drug, or IND, application, 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 I. 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 II. 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 III. 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 IV 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. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

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

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

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

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

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

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

Orphan drug designation

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

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

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

Expedited development and review programs

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

that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

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

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

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

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

Post-approval requirements

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

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other

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

Biosimilars and exclusivity

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

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.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

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, Europe, which may include, for instance, applicable 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.

In order to market our future product candidates in the European Economic Area (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein) (the "EEA"), and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal product candidates can only be commercialized after obtaining a Marketing Authorization ("MA"). There are two types of marketing authorizations:

- the "Community MA," which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Product candidates for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of product candidates, such as biotechnology medicinal product candidates, orphan medicinal product candidates and medicinal product candidates indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for product candidates containing a new active substance not yet authorized in the EEA, 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; and
- "National MAs," which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, 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 a Member State of the EEA, 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 above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and marketing exclusivity. In the EEA, new product candidates authorized for marketing, or reference product candidates, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization 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 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization 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.

Pediatric investigation plan. In the EEA, marketing authorization applications 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 ("PIP"), agreed with the EMA's Pediatric

Committee (“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 marketing authorization is obtained in all Member States of the EU 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.

Orphan drug designation. In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically-debilitating condition affecting not more than five in 10,000 persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously-debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, the EMA or the competent authorities of the Member States, cannot accept another application for a marketing authorization, or grant a marketing authorization, 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.

This period of orphan 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, i.e. 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 where another product has market exclusivity can happen only in selected cases, such as, for example, demonstration of “clinical superiority” by a similar medicinal product, inability of a manufacturer to supply sufficient quantities of the first product or where the manufacturer itself gives consent. A company may voluntarily remove a product from the orphan register. Medicinal products or medicinal product candidates designated as orphan are eligible for incentives made available by the EU and its Member States to support research into, development and availability of orphan medicinal products.

Adaptive pathways. The EMA has an adaptive pathways program which allows for early and progressive patient access to a medicine. The adaptive pathways concept is an approach to medicines approval that aims to improve patients’ access to medicines in cases of high unmet medical need. To achieve this goal, several approaches are envisaged: identifying small populations with severe disease where a medicine’s benefit-risk balance could be favorable; making more use of real-world data where appropriate to support clinical trial data; and involving health technology assessment bodies early in development to increase the chance that medicines will be recommended for payment and ultimately covered by national healthcare systems. The adaptive pathways concept applies primarily to

treatments in areas of high medical need where it is difficult to collect data via traditional routes and where large clinical trials would unnecessarily expose patients who are unlikely to benefit from the medicine. The approach builds on regulatory processes already in place within the existing EU legal framework. These include: scientific advice; compassionate use; the conditional approval mechanism (for medicines addressing life-threatening conditions); patient registries and other pharmacovigilance tools that allow collection of real-life data and development of a risk-management plan for each medicine.

The adaptive pathways program does not change the standards for the evaluation of benefits and risks or the requirement to demonstrate a positive benefit-risk balance to obtain marketing authorization.

PRIME scheme. In July 2016, the EMA launched the PRIME scheme. PRIME is 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 however not guaranteed. The benefits of a PRIME designation includes the appointment of a rapporteur from the Committee for Medicinal Product candidates for Human Use before submission of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify product candidates for accelerated review earlier in the application process.

Other Healthcare Laws

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

Coverage and Reimbursement

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

The U.S. government, state legislatures and foreign governments have also continued implementing cost-containment programs, including price controls, restrictions on coverage and

reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

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

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

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. For example, the United States Supreme Court is currently reviewing the U.S. Court of Appeals for the 5th Circuit ruling that the individual mandate was unconstitutional and to determine the constitutionality of the ACA in its entirety. 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 December 31, 2021 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 and executive orders issued by the former Trump administration 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. The likelihood of success of these and other measures initiated by the former Trump administration is uncertain, particularly in light of the new Biden administration. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

Data Privacy & Security

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

Employees and Human Capital Resources

As of April 30, 2021, we had 54 full-time employees and 2 part-time employees. Of our full-time employees, 40 employees are engaged in research and development activities and 14 are engaged in general and administrative activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our employees. We believe our success depends on our ability to attract, retain, develop and motivate diverse highly skilled personnel. In particular, we depend upon the personal efforts and abilities of the principal members of our senior management to partner effectively as a team, and to provide strategic direction, develop our business, manage our operations and maintain a cohesive and stable work environment. We also rely on qualified managers and skilled employees, such as scientists, engineers and laboratory technicians, with technical expertise in operations, scientific knowledge, engineering skills and quality management experience in order to operate our business successfully.

Our compensation program is designed to retain, motivate and, as needed, attract highly qualified employees. Accordingly, we use a mix of competitive base salary, cash-based annual incentive compensation, performance-based equity compensation awards and other employee benefits.

Facilities

Our principal office is located at 20 Acorn Park Drive, Cambridge, Massachusetts 02140, where we occupy approximately 24,000 square feet of office and laboratory space under a shared space arrangement that currently expires in July 2022. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

We are not subject to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors.

Name	Age	Position
Executive Officers		
Mahesh Karande	48	President and Chief Executive Officer and Director
Roger Sawhney, M.D.	51	Chief Financial Officer
Thomas McCauley, Ph.D.	52	Chief Scientific Officer
Directors		
Noubar B. Afeyan, Ph.D.	58	Chairman of the Board of Directors
David A. Berry, M.D., Ph.D.	43	Director
Elliott M. Levy, M.D.	62	Director
John Mendlein, Ph.D., J.D.	61	Director
Mary T. Szela	57	Director
Richard A. Young, Ph.D.	67	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

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. From March 2010 to April 2017, Mr. Karande held senior leadership roles at Novartis, including VP and Franchise Head, US Oncology, President Novartis Africa and President Novartis Egypt. Mr. Karande holds an M.B.A. from the Wharton School, University of Pennsylvania. He is also a graduate of the Georgia Institute of Technology where he completed his M.S. in engineering and the University of Bombay where he completed his undergraduate studies in engineering. We believe that Mr. Karande's extensive life science and leadership experience qualifies him to serve on our board of directors.

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

Thomas McCauley, Ph.D. has served as the Chief Scientific Officer of our company since July 2019. From September 2018 to July 2019, Dr. McCauley served as Chief Scientific Officer of Zikani Therapeutics (formerly Macrolide Pharmaceuticals) 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 made significant contributions 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.

Non-Employee Directors

Noubar B. Afeyan, Ph.D. was a co-founder and serves as chairman of our board and has been a director since July 2016. In 1999, Dr. Afeyan founded Flagship Pioneering and serves as its Senior Managing Partner and Chief Executive Officer. Since August 2009, Dr. Afeyan has served on the board of directors of Moderna, Inc. and since April 2013 has served on the board of directors of Rubius Therapeutics, Inc. He currently serves on the boards of numerous privately held companies, and has previously served on the boards of numerous privately and publicly held companies, including Evelo Biosciences, Inc., Kaleido Biosciences, Inc. and Seres Therapeutics, Inc. He received a Ph.D. in biochemical engineering from the Massachusetts Institute of Technology and a B.S. in chemical engineering from McGill University. Dr. Afeyan is currently a visiting lecturer of business administration at Harvard Business School. We believe that Dr. Afeyan's significant experience co-founding, leading, and investing in numerous biotechnology companies make him qualified to serve on our board of directors.

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

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

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

Mary T. Szela has served as a member of our board of directors since June 2019. Ms. Szela currently serves as the Chief Executive Officer and President of TriSalus Life Sciences, Inc. (formerly Surefire Medical, Inc.), a privately held m 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 Kura Oncology, Inc. since November 2018, Prometheus Biosciences since March of 2021, Coherus Biosciences since 2014, Alimera Sciences Inc. since June 2018 and TriSalus Life Sciences, Inc. since January 2018. She also previously served as a member of the board of directors of Receptos, Inc. from June 2014 to July 2015, Novo Nordisk from March 2014 to March 2017, and Macrolide Pharmaceuticals, from March 2018 to July 2019. Ms. Szela earned an M.B.A. in Business and a B.S. in nursing, both from the University of Illinois. We believe that Ms. Szela's extensive leadership experience in the pharmaceutical industry qualifies her to serve on our board of directors.

Richard A. Young, Ph.D. has served on our board of directors since August 2017. He has been a member of the Whitehead Institute and Professor of Biology at the Massachusetts Institute of Technology since 1984. Dr. Young currently serves as a member of the boards of directors of Syros Pharmaceuticals, Inc. since November 2011, Camp4 Therapeutics, Inc. since February 2016, and Dewpoint Therapeutics, Inc. since October 2020. In May 2012, he was elected into the National Academy of Sciences and in October of 2019, he was elected to the National Academy of Medicine. Dr. Young received his Ph.D. in molecular biophysics and biochemistry from Yale University. We believe Dr. Young is qualified to serve on our board of directors because of his scientific expertise.

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of seven members. Our board of directors has determined that, of our seven directors, , , , , and do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is

defined under the rules of the Nasdaq Stock Market LLC, or Nasdaq. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

In accordance with our restated certificate of incorporation that will go into effect upon the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be , and , and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be and , and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be and , and their terms will expire at the third annual meeting of stockholders following this offering.

Our restated certificate of incorporation that will go into effect upon the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock entitled to vote in the election of directors.

Our directors were elected to and currently serve on the board pursuant to a voting agreement among us and several of our largest stockholders. See “Certain Relationships and Related Party Transactions—Voting Agreement.” This agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors.

Board Leadership Structure

Our board of directors is currently chaired by Dr. Afeyan. Our corporate governance guidelines provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. The lead director’s responsibilities include, but are not limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as

through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

Board Committees

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors. Upon our listing on the Nasdaq Global Market, each committee's charter will be available under the Corporate Governance section of our website at *www.omegatherapeutics.com*. 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 prospectus.

Audit Committee

The audit committee's responsibilities include, among other things:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities Exchange Commission, or SEC, rules.

The members of our audit committee are , and . serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable listing rules of Nasdaq, or the Nasdaq rules. Our board of directors has determined that and meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq rules. Our board of directors has determined that is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules.

Compensation Committee

The compensation committee's responsibilities include:

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our CEO and our other executive officers;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and
- preparing the annual compensation committee report required by SEC rules, to the extent required.

The members of our compensation committee are , and . serves as the chairperson of the committee. Our board of directors has determined that each of , and is independent under the applicable Nasdaq rules, including the Nasdaq rules specific to membership on the compensation committee, and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include, among other things:

- identifying individuals qualified to become board members;
- recommending to our board of directors the persons to be nominated for election as directors and to each board committee;
- developing and recommending to our board of directors corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time; and
- overseeing a periodic evaluation of our board of directors.

The members of our nominating and corporate governance committee are , and . serves as the chairperson of the committee. Our board of directors has determined that , and are independent under the applicable Nasdaq rules and the SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as a director or member of our compensation committee during the fiscal year ended December 31, 2020.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal

accounting officer or controller, or persons performing similar functions. Upon our listing on the Nasdaq Global Market, our code of business conduct and ethics will be available under the Corporate Governance section of our website at *www.omegatherapeutics.com*. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. 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 prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2020 Summary Compensation Table" below. In 2020, our "named executive officers" and their positions were as follows:

- Mahesh Karande, President and Chief Executive Officer;
- Roger Sawhney, M.D., Chief Financial Officer; and
- Thomas McCauley, Ph.D., Chief Scientific Officer.

2020 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Mahesh Karande President and Chief Executive Officer	2020	$482,620	$126,577	$ 241,310	$ 86,866	$ 937,373
Roger Sawhney, M.D. Chief Financial Officer	2020	$213,000(4)	$684,121	$ 74,550	$ 36,630	$1,008,301
Thomas McCauley, Ph.D. Chief Scientific Officer	2020	$353,365	—	$ 123,678	—	$ 477,043

(1) Amounts reflect the full grant date fair value of option awards granted during 2020 computed in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of option awards in Note 12 to the audited financial statements included in this prospectus.

(2) Amounts shown represent each named executive officer's annual bonus earned with respect to fiscal year 2020. Refer to "—2020 Annual bonuses" below for additional information regarding the Company's annual bonus program for 2020.

(3) The amounts reported for Mr. Karande and Dr. Sawhney reflect reimbursements for travel and lodging.

(4) Dr. Sawhney commenced employment as of Chief Financial Officer in May 2020. His annual base salary for 2020 was $355,000.

Narrative disclosure to summary compensation table

2020 Salaries

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Our board of directors increased the annual base salary for Mr. Karande from $472,000 to $486,160 and increased the annual base salary for Dr. McCauley from $350,000 to $354,487, in each case, effective April 1, 2020. Dr. Sawhney commenced employment with us in May 2020 with an initial annual base salary of $355,000.

2020 Annual bonuses

Each of Mr. Karande, Dr. Sawhney and Dr. McCauley was eligible to receive an annual bonus under the annual bonus program we maintain for all employees. For 2020, the target bonus amounts,

expressed as a percentage of base salary, for Mr. Karande, Dr. Sawhney and Dr. McCauley were 50%, 35% and 35%, respectively. Annual bonuses for 2020 were based on the attainment of both corporate and individual performance goals as recommended by the compensation committee and determined by the board of directors. The corporate performance goals for 2020 were based on the achievement of company growth metrics and developing the Company's research and development programs. The individual performance goals for 2020 were based on each named executive officer's performance in their individually assigned duties and responsibilities. For 2020, each named executive officer received a bonus equal to 100% of his target amount, or $241,310 for Mr. Karande, $74,550 for Dr. Sawhney and $123,678 for Dr. McCauley. Dr. Sawhney's bonus was pro-rated to reflect the portion of the calendar year during which he was employed.

Equity compensation

We generally offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options generally allow employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant, as determined by the board of directors. The stock options granted to our named executive officers generally vest as to 25% of the underlying shares on the first anniversary of the date of grant and in equal quarterly installments over the following three years. Historically, our stock options have been intended to qualify as "incentive stock options," to the extent permitted under the Internal Revenue Code, or the Code.

Prior to this offering, we have granted equity awards under our 2017 Equity Incentive Plan, referred to below as the 2017 Plan. Mr. Karande and Dr. Sawhney both received incentive equity grants in fiscal year 2020 under the 2017 Plan. On January 26, 2020, Mr. Karande was granted 1,232,999 stock options, which vest 25% on April 1, 2020, and the remainder in 12 equal quarterly installments thereafter, subject to Mr. Karande's continued employment through each applicable vesting date. On September 30, 2020, Dr. Sawhney was granted 1,507,687 stock options, which vest 25% on May 26, 2021 and the remainder in 12 equal quarterly installments thereafter, subject to Dr. Sawhney's continued employment through each applicable vesting date. Refer to the "Outstanding Equity Awards at 2020 Fiscal Year-End" below for additional information regarding these grants.

Effective on the day prior to our first public trading date, we intend to adopt a 2021 Incentive Award Plan, referred to below as the 2021 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of its affiliates and to enable our company and certain of its affiliates to obtain and retain the services of these individuals. Once the 2021 Plan becomes effective, we will cease making grants under the 2017 Plan. However, the 2017 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. For additional information about the 2017 Plan and the 2021 Plan, please see the section titled "Incentive Compensation Plans" below.

Employee and retirement benefits

We currently offer broad based health and welfare benefits, including health, life, disability, vision, and dental insurance to our named executive officers to the same extent as our other full-time employees, subject to the terms and eligibility requirements of those plans. We also reimburse Mr. Karande and Dr. Sawhney for travel and lodging expenses they incur in connection with the performance of their duties. In addition to the health and welfare benefits, we maintain a 401(k) retirement plan for our full-time employees, including our named executive officers. The 401(k) plan permits us to make discretionary employer contributions; however, we did not make any employer contributions in 2020. Other than the 401(k) plan, we do not provide any qualified or non-qualified retirement or deferred compensation benefits to our employees, including our named

executive officers. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees.

Agreements with our named executive officers

Our named executive officers are each party to an employment or letter agreement with us that sets forth the terms and conditions of his employment. Pursuant to his offer letter, Mr. Karande is eligible to receive a one-time relocation bonus of $200,000 if he relocates his primary residence to the Boston, Massachusetts area by December 31, 2021, which will be payable within 30 days following the date of Mr. Karande's relocation; provided, if Mr. Karande's employment is terminated for a reason other than due to an Involuntary Termination (as defined in his offer letter) (i) prior to the first anniversary of the payment date of the relocation bonus, he will be required to repay the full gross amount of the relocation bonus or (ii) after the first anniversary and prior to the second anniversary of the payment date of the relocation bonus, he will be required to repay 75% of the gross amount of the relocation bonus. We expect to enter into new employment agreements with the named executive officers that will supersede their existing agreements effective upon the effectiveness of the registration statement relating to this offering. The terms of these new agreements are not yet known.

Outstanding Equity Awards at 2020 Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2020.

		Option Awards			
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date
Mahesh Karande	6/24/2019(1)	1,119,192	2,365,322	0.14	6/23/2029
	1/26/2020(1)	462,374	770,625	0.16	1/25/2030
Roger Sawhney, M.D.	9/30/2020(2)	—	1,507,687	0.68	9/29/2030
Thomas McCauley, Ph.D.	9/17/2019(3)	348,141	765,912	0.16	9/16/2029

(1) The option vests over four years, with 25% of the shares vested on April 1, 2020, and the remainder vesting in equal quarterly installments thereafter, subject to continued employment through each applicable vesting date.

(2) The option vests over four years, with 25% of the shares vesting on May 26, 2021, and the remainder vesting in equal quarterly installments thereafter, subject to continued employment through each applicable vesting date.

(3) The option vests over four years, with 25% of the shares vested on July 29, 2020, and the remainder vesting in equal quarterly installments thereafter, subject to continued employment through each applicable vesting date.

2020 Director Compensation

The table below shows all compensation to our non-employee directors during the year ended December 31, 2020. Mahesh Karande, our President and Chief Executive Officer, is also a member of our board of directors, but he does not receive any additional compensation for his service as a director. Information regarding Mr. Karande's 2020 compensation is included in the "2020 Summary Compensation Table", "Outstanding Equity Awards at 2020 Fiscal Year-End" table and associated narrative disclosure above.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Noubar Afeyan, Ph.D.(2)	—	—	—	—
David Berry, M.D., Ph.D.(2)	—	—	—	—
John Mendlein, Ph.D., J.D.	—	133,800	—	133,800
Mary Szela	—	—	—	—
Richard A. Young, Ph.D.(3)	—	—	120,000	120,000
Paul Peter Tak, Ph.D.(4)	—	—	—	—

(1) This column represents the aggregate grant date fair value of the stock options in the fiscal year, calculated in accordance with ASC Topic 718, rather than the amounts paid to or realized by the non-employee director. We provide information regarding the assumptions used to calculate the value of option awards in Note 12 to the audited financial statements included in this prospectus.
(2) Drs. Afeyan and Berry, who are affiliated with our investors, do not receive compensation in respect of their service as members of our board of directors.
(3) We are party to a founder consulting agreement with Dr. Young under which he provides advisory services to us and we pay him $120,000 annually. Dr. Young did not receive any additional compensation for his service as a director.
(4) Dr. Tak resigned from our board of directors effective June 17, 2020.

The table below shows the aggregate numbers of option awards (exercisable and unexercisable) held as of December 31, 2020 by each non-employee director. Our non-employee directors did not hold any unvested restricted stock or restricted stock units as of December 31, 2020.

Name	Option Awards Outstanding at 2020 Fiscal Year End(#)
Noubar Afeyan, Ph.D.	—
David Berry, M.D., Ph.D.	—
John Mendlein, Ph.D., J.D.	836,252
Mary Szela	316,676
Richard A. Young, Ph.D.	—
Paul Peter Tak, Ph.D.	—

Incentive Compensation Plans

The following summarizes the material terms of 2021 Plan, and the 2021 Employee Stock Purchase Plan, which will be the long-term incentive compensation plans in which our directors and named executive officers are eligible to participate following the consummation of this offering, and the 2017 Plan, under which we have previously made periodic grants of equity and equity-based awards to our directors and named executive officers.

2021 Incentive Award Plan

Effective the day prior to the first public trading date of our common stock, we intend to adopt and ask our stockholders to approve the 2021 Plan, under which we may grant cash and equity-based incentive awards to eligible service providers in order to attract, retain and motivate the persons who make important contributions to our company. The material terms of the 2021 Plan are summarized below.

Eligibility and Administration

Our employees, consultants and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2021 Plan. The 2021 Plan will be administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to the limitations imposed under the 2021 Plan, Section 16 of the Exchange Act, stock exchange rules and other applicable laws. The plan administrator will have the authority to take all actions and make all determinations under the 2021 Plan, to interpret the 2021 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2021 Plan as it deems advisable. The plan administrator will also have the authority to grant awards, determine which eligible service providers receive awards and set the terms and conditions of all awards under the 2021 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2021 Plan.

Shares Available for Awards

An aggregate of shares of our common stock will initially be available for issuance under the 2021 Plan. The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year beginning in 2022 and ending in and including 2031, equal to the lesser of (A) % of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares determined by our board of directors. No more than shares of common stock may be issued under the 2021 Plan upon the exercise of incentive stock options, or ISOs. Shares issued under the 2021 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2021 Plan or the 2017 Plan, expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2021 Plan. Awards granted under the 2021 Plan in substitution for any options or other stock or stock-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2021 Plan, but may count against the maximum number of shares that may be issued upon the exercise of ISOs.

Awards

The 2021 Plan provides for the grant of stock options, including ISOs, and nonqualified stock options, or NSOs, stock appreciation rights, or SARs, restricted stock, dividend equivalents, restricted stock units, or RSUs, and other stock or cash based awards. Certain awards under the 2021 Plan may constitute or provide for payment of "nonqualified deferred compensation" under Section 409A of the Code. All awards under the 2021 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

- Stock Options and SARs. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR. The exercise price of a stock option or SAR will not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain

significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).

- Restricted Stock and RSUs. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted stock and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2021 Plan.
- Other Stock or Cash Based Awards. Other stock or cash based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock or other property. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other stock or cash based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

Performance Criteria

The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2021 Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the company's performance or the performance of a subsidiary, division, business segment or business unit of the company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an

event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

Certain Transactions

In connection with certain corporate transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2021 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2021 Plan and replacing or terminating awards under the 2021 Plan. In addition, in the event of certain non-reciprocal transactions with our stockholders, the plan administrator will make equitable adjustments to awards outstanding under the 2021 Plan as it deems appropriate to reflect the transaction.

Provisions of the 2021 Plan Relating to Director Compensation.

The 2021 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2021 Plan's limitations. Prior to commencing this offering, we intend to approve and implement a compensation program for our non-employee directors, which is described above under the heading "Director Compensation." Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value of any equity awards granted under the 2021 Plan as compensation for services as a non-employee director during any fiscal year may not exceed $ in the fiscal year of the non-employee director's initial service and $ in any other fiscal year. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, subject to the limitations in the 2021 Plan.

Plan Amendment and Termination

Our board of directors may amend or terminate the 2021 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2021 Plan, may materially and adversely affect an award outstanding under the 2021 Plan without the consent of the affected participant and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator may, without the approval of our stockholders, amend any outstanding stock option or SAR to reduce its price per share, including in the context of corporate transactions or equity restructurings, as described above. The 2021 Plan will remain in effect until the tenth anniversary of its effective date, unless earlier terminated by our board of directors. No awards may be granted under the 2021 Plan after its termination.

Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments

The plan administrator may modify awards granted to participants who are foreign nationals or employed outside the United States or establish subplans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions. All awards will be subject to any

company claw-back policy as set forth in such claw-back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2021 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2021 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2021 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, shares of our common stock that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

2021 Employee Stock Purchase Plan

Effective the day prior to the first public trading date of our common stock, we intend to adopt and ask our stockholders to approve the 2021 Employee Stock Purchase Plan, or the 2021 ESPP, the material terms of which are summarized below.

Shares Available for Awards; Administration

A total of shares of our common stock will initially be reserved for issuance under the 2021 ESPP. In addition, the number of shares available for issuance under the 2021 ESPP will be annually increased on January 1 of each calendar year beginning in 2022 and ending in and including 2031, by an amount equal to the lesser of (A) % of the shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors, provided that no more than shares of our common stock may be issued under the 2021 ESPP. Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the 2021 ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the 2021 ESPP.

Eligibility

All of our employees are eligible to participate in the 2021 ESPP. However, an employee may not be granted rights to purchase stock under our 2021 ESPP if the employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

Grant of Rights

The 2021 ESPP is intended to qualify under Section 423 of the Code and stock will be offered under the 2021 ESPP during offering periods. The length of the offering periods under the 2021 ESPP will be determined by the plan administrator and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the offering period. Offering periods under the 2021 ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The 2021 ESPP permits participants to purchase common stock through payroll deductions of up to a specified percentage of their eligible compensation. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period. In addition, no employee will be permitted to accrue the right to purchase stock under the 2021 ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the 2021 ESPP at any time during a specified period prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the 2021 ESPP other than by will or the laws of descent and distribution, and are generally exercisable only by the participant.

Certain Transactions

In the event of certain non-reciprocal transactions or events affecting our common stock, the plan administrator will make equitable adjustments to the 2021 ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

Plan Amendment

The plan administrator may amend, suspend or terminate the 2021 ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the 2021 ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the 2021 ESPP or changes the 2021 ESPP in any manner that would cause the 2021 ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code.

2017 Plan

Our board of directors and stockholders have approved our 2017 Plan, under which we may grant stock options, restricted stock awards, restricted stock units and other stock-based awards to employees, directors and consultants of our company or its subsidiaries. We have reserved a total of 24,200,000 shares of our common stock for issuance under the 2017 Plan.

Following the effectiveness of the 2021 Plan, we will not make any further grants under the 2017 Plan. However, the 2017 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of our common stock subject to awards granted under the 2017 Plan that are forfeited, lapse unexercised or are settled in cash and which following the effective date of the 2021 Plan are not issued under the 2017 Plan will be available for issuance under the 2021 Plan. As of , a total of shares of our common stock were subject to outstanding stock options issued under the 2017 Plan and no other awards were outstanding under the 2017 Plan.

Eligibility and Administration

Our employees, officers, and directors, along with consultants to the Company, are eligible to receive awards under the 2017 Plan. Our board of directors or a committee thereof is authorized to

administer the 2017 Plan. Subject to the express terms and conditions of the 2017 Plan, the plan administrator has the authority to make all determinations and interpretations under the plan, prescribe all forms for use with the plan and adopt, amend and repeal rules, guidance and practices for the administration of the 2017 Plan. Our board may delegate to one or more committees of our board. The plan administrator also sets the terms and conditions of all awards under the plan, including any vesting and vesting acceleration conditions.

Awards

The 2017 Plan provides for the grant of stock options (including NSOs and ISOs), restricted stock, restricted stock units and other stock-based awards.

Certain Transactions

The plan administrator has broad discretion to adjust the provisions of the 2017 Plan and the terms and conditions of existing and future awards, including with respect to the aggregate number and kind of shares subject to the 2017 Plan and awards granted pursuant to the 2017 Plan and the purchase or exercise price of awards granted pursuant to the 2017 Plan, in order to prevent substantial dilution or enlargement of the rights of participants under the 2017 Plan in the event of certain transactions and events affecting our common stock, such as a reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of assets of the Company, or sale or exchange of the Company's common stock or other securities of the Company, issuance of warrants or other rights to purchase common stock of the Company or other securities of the Company. The plan administrator may also provide for the assumption, substitution, acceleration, replacement or cash-out of awards in the event of the transactions mentioned above.

Amendment and Termination

Our board of directors or compensation committee (to the extent permitted by law) may suspend or terminate the 2017 Plan at any time and from time to time. Furthermore, we must generally obtain stockholder approval to increase the number of shares available under the 2017 Plan (other than in connection with certain corporate events, as described above) or to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule).

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2018 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Preferred Stock Financings

Series A Preferred Stock Financing. From August 2017 to June 2019, we issued and sold to investors in private placements an aggregate of 56,775,232 shares of our Series A preferred stock at a purchase price of $0.50 per share, for aggregate consideration of approximately $28.4 million.

Series B Preferred Stock Financing. From January 2020 to August 2020, we issued and sold to investors in private placements an aggregate of 32,399,999 shares of our Series B preferred stock at a purchase price of $1.50 per share, for aggregate consideration of approximately $48.6 million.

Series C Preferred Stock Financing. In March 2021, we issued and sold to investors in private placements an aggregate of 41,833,328 shares of our Series C preferred stock at a purchase price of $3.00 per share, for aggregate consideration of approximately $125.5 million.

The following table sets forth the aggregate number of shares of our capital stock acquired by beneficial owners of more than 5% of our capital stock in the financing transactions described above. Each share of our Series A preferred stock, Series B preferred stock and Series C preferred stock identified in the following table will convert into shares of common stock upon the closing of this offering.

Participants	Series A Preferred Stock	Series B Preferred Stock	Series C Preferred Stock
5% or Greater Stockholders(1)			
Entities affiliated with Flagship Pioneering	56,775,232	20,000,000	8,333,333
HarbourVest Partners L.P.	—	6,666,667	3,333,333

(1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal Stockholders."

Some of our directors are associated with our principal stockholders as indicated in the table below:

Director	Principal Stockholder
Noubar B. Afeyan, Ph.D.	Entities affiliated with Flagship Pioneering
John Mendlein, Ph.D., J.D.	Entities affiliated with Flagship Pioneering
David A. Berry, M.D., Ph.D.	Entities affiliated with Flagship Pioneering

Investor Rights Agreement

We entered into a Second Amended and Restated Investors' Rights Agreement in March 2021 with the holders of our preferred stock, including entities with which certain of our directors are related.

The agreement provides, among other things, for certain rights relating to the registration of such holders' common stock, including shares issuable upon conversion of preferred stock. See "Description of Capital Stock—Registration Rights" for additional information.

Voting Agreement

We entered into a Second Amended and Restated Voting Agreement in March 2021, pursuant to which the following directors were elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Noubar B. Afeyan, Ph.D., David A. Berry, M.D., Ph.D., John Mendlein, Ph.D., J.D., Richard A. Young, Ph.D., Mary T. Szela and Mahesh Karande. Mahesh Karande was selected to serve on our board of directors in his capacity as our chief executive officer. Drs. Afeyan and Berry were initially selected to serve on our board of directors as representatives of holders of our preferred stock, as designated by entities affiliated with Flagship Pioneering. Ms. Szela and Drs. Mendlein and Young were selected to serve on our board of directors as independent directors, as designated by the holders of a majority of the voting power of the outstanding shares of preferred stock.

The voting agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under "Management —Board Composition and Election of Directors."

Flagship Management Service Agreement

In July 2016, we entered into a ten-year management service agreement with Flagship Pioneering, or Flagship to provide management services, including accounting, human resources, information technology, legal, and consultation. We also agreed to reimburse Flagship for certain expenses, including insurance and benefits, partner and related fees, and software licenses incurred on our behalf. For the years ended December 31, 2020 and 2019, we paid Flagship $0.9 million and $1.1 million, respectively, in management services fees and other reimbursements.

Flagship License Agreement

In March 2019, we entered into a license agreement with Flagship Pioneering Innovations V, Inc., or Flagship, an affiliate of certain beneficial owners of more than 5% of our capital stock, pursuant to which we received an exclusive, worldwide, royalty-bearing, transferable, sublicensable license under certain patent rights owned or controlled by Flagship. There were no payments made under the agreement during the years ended December 31, 2020 and 2019. For more information regarding the agreement with Flagship, see "Business — License Agreements."

Whitehead License Agreements

In May 2019, we entered into an exclusive license agreement with the Whitehead Institute for Biomedical Research, or WIBR, pursuant to which we received an exclusive, worldwide, royalty-bearing, sublicensable license under certain patent rights owned or controlled by WIBR. We made payments under the agreement of less than $0.1 million in each of the years ended December 31, 2020 and 2019. The patents in-licensed by us from WIBR pursuant to the agreement claim inventions created by, among others, Dr. Young, one of our directors. Pursuant to WIBR's policy on the ownership, distribution and commercial development of WIBR's technology, or the WIBR Policy, inventors of intellectual property invented at WIBR, including the inventors of patents licensed to us

under the agreement, are entitled to a portion of the net royalty income derived from such inventions. Accordingly, pursuant to the WIBR Policy, Dr. Young is entitled to receive a portion of the amounts we pay to WIBR under the agreement. Accordingly, Dr. Young received approximately $2,000 and $2,800 from WIBR under the WIBR Policy during the years ended December 31, 2020 and 2019, respectively, due to payments we made under the agreement. For more information regarding the agreement with WIBR, see “Business — License Agreements.”

In May 2019, we entered into a co-exclusive license agreement with WIBR pursuant to which we received a co-exclusive, worldwide, royalty-bearing, sublicensable license under certain patent rights owned or controlled by WIBR. We made payments under the agreement of less than $0.1 million during each of the years ended December 31, 2020 and 2019. The patents in-licensed by us from WIBR pursuant to the agreement claim inventions created by, among others, Dr. Young, one of our directors. Pursuant to the WIBR Policy, inventors of intellectual property invented at WIBR, including the inventors of patents licensed to us under the agreement, are entitled to a portion of the net royalty income derived from such inventions. Accordingly, pursuant to the WIBR Policy, Dr. Young is entitled to receive a portion of the amounts we pay to WIBR under the agreement. Accordingly, Dr. Young received approximately $1,000 and $1,700 from WIBR under the WIBR Policy during the years ended December 31, 2020 and 2019, respectively, due to payments we made under the agreement. For more information regarding the agreement with WIBR, see “Business — License Agreements.”

Sublease Agreement with LARONDE, Inc. (formerly known as VL50, Inc.)

In August 2020, we entered into a sublease agreement with LARONDE, Inc., a company affiliated with certain beneficial owners of more than 5% of our capital stock, for a portion of laboratory and office space in Cambridge, Massachusetts. The term of the sublease agreement commenced on August 27, 2020 and terminates on September 30, 2024.

Sublease Agreement with Cygnal Therapeutics, Inc.

In September 2019, we entered into a sublease agreement with Cygnal Therapeutics, Inc., a company affiliated with certain beneficial owners of more than 5% of our capital stock, for a portion of laboratory and office space in Cambridge, Massachusetts. The term of the sublease agreement commenced on September 20, 2019 and terminates on September 30, 2021.

Shared Space Arrangement with Senda Biosciences (formerly known as Kintai Therapeutics, Inc.)

In July 2020, we entered into a shared space arrangement with Kintai Therapeutics, Inc., a company affiliated with certain beneficial owners of more than 5% of our capital stock, for a portion of laboratory and office space in Cambridge, Massachusetts. The term of the shared space arrangement commenced on August 1, 2020 and terminates on July 31, 2022.

Indemnification Agreements

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer. For further information, see “Executive and Director Compensation—Limitations of Liability and Indemnification.”

Policies and Procedures for Related Person Transactions

Our board of directors will adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year, or, for so long as we qualify as a smaller reporting company, the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section will have occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, as of , 2021 by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on shares of common stock outstanding as of , 2021, assuming the conversion of all outstanding shares of our preferred stock into shares of our common stock. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of , 2021 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 20 Acorn Park Drive, Cambridge, Massachusetts 02140. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned	
		Before this Offering	After this Offering
5% or Greater Stockholders			
Entities affiliated with Flagship Pioneering(1)		%	%
HarbourVest Partners L.P.(2)		%	%
Named Executive Officers and Directors			
Mahesh Karande(3)		%	%
Roger Sawhney, M.D.(4)		%	%
Thomas McCauley, Ph.D.(5)		%	%
Noubar B. Afeyan, Ph.D.(1)		%	%
David A. Berry, M.D., Ph.D.		%	%
Elliott M. Levy, M.D.(6)		%	%
John Mendlein, Ph.D., J.D.(7)		%	%
Mary T. Szela(8)		%	%
Richard A. Young, Ph.D.		%	%
All executive officers and directors (10 persons)(9)		%	%

* Less than 1%.

(1) Includes (a) shares held by Flagship VentureLabs V, L.P. (“VentureLabs V”), (b) shares held by Flagship Ventures Fund V, L.P. (“Flagship Fund V”), (c) shares held by Flagship V VentureLabs Rx Fund, L.P. (“Flagship Fund V Rx”), shares held by Flagship Pioneering Fund VI, L.P. (“Flagship Fund VI”), (d) shares held by

Flagship Pioneering Special Opportunities Fund II, L.P. ("Flagship Opportunities Fund II"), (e) shares held by Nutritional Health LTP Fund, L.P. ("Nutritional LTP") and (f) shares held by FPN, L.P. ("FPN Fund" and together with VentureLabs V, Flagship Fund V, Flagship Fund V Rx, Flagship Fund VI, Flagship Opportunities Fund II and Nutritional LTP, the "Flagship Funds"). Flagship Fund V is a member of VentureLabs V. VentureLabs V Manager LLC ("VentureLabs V Manager") is the manager of VentureLabs V. Flagship Pioneering, Inc. ("Flagship Pioneering") is the manager of VentureLabs V Manager. The General Partner of Flagship Fund V and Flagship Fund V Rx is Flagship Ventures Fund V General Partner LLC ("Flagship V GP"). The General Partner of Flagship Pioneering VI is Flagship Pioneering Fund VI General Partner LLC ("Flagship Pioneering VI GP"). The General Partner of Flagship Opportunities Fund II is Flagship Pioneering Special Opportunities Fund II General Partner LLC ("Flagship Opportunities Fund II GP"). The general partner of FPN Fund is FPN General Partner LLC ("FPN GP"). The manager of Flagship Pioneering VI GP, Flagship Opportunities Fund II GP, and FPN GP is Flagship Pioneering. The general partner of Nutritional LTP is Nutritional Health LTP Fund General Partner LLC ("Nutritional LTP GP" and, together with VentureLabs V Manager, Flagship Pioneering, Flagship Pioneering VI GP, Flagship Opportunities Fund II GP and FPN GP, the "Flagship General Partners"). Noubar B. Afeyan, Ph.D. ("Dr. Afeyan") is the sole director of Flagship Pioneering and may be deemed to have beneficial ownership of all the shares held by VentureLabs V, Flagship Fund VI, Flagship Opportunities Fund II and FPN Fund. In addition, Dr. Afeyan serves as the sole manager of Flagship V GP and is the sole member and manager of Nutritional LTP GP and may be deemed to have beneficial ownership of all the shares held by Flagship Fund V, Flagship Fund V Rx and Nutritional LTP. None of the Flagship General Partners nor Dr. Afeyan directly own any of the shares held by the Flagship Funds, and each of the Flagship General Partners and Dr. Afeyan disclaims beneficial ownership of such shares except to the extent of its or his pecuniary interest therein. The mailing address of the Flagship Funds is 55 Cambridge Parkway, Suite 800E, Cambridge, MA 02142.

(2) Includes shares of common stock that can be acquired pursuant to the conversion of Series B Preferred Stock and Series C Preferred Stock held by SMRS-TOPE LLC. SMRS-TOPE LLC is ultimately owned by certain retirement systems associated with the State of Michigan. SMRS-TOPE LLC is managed by HarbourVest Partners, L.P., which is a registered investment advisor that has many accounts and funds under management. The mailing address of SMRS-TOPE LLC is c/o HarbourVest Partners, LLC, One Financial Center, Boston, MA 02111.

(3) Includes shares of common stock that can be acquired pursuant to outstanding share options, including options that will be exercisable within 60 days of .

(4) Includes shares of common stock that can be acquired pursuant to outstanding share options, including options that will be exercisable within 60 days of .

(5) Includes shares of common stock that can be acquired pursuant to outstanding share options, including options that will be exercisable within 60 days of .

(6) Includes shares of common stock that can be acquired pursuant to outstanding share options, including options that will be exercisable within 60 days of .

(7) Includes shares of common stock that can be acquired pursuant to outstanding share options, including options that will be exercisable within 60 days of .

(8) Includes shares of common stock that can be acquired pursuant to outstanding share options, including options that will be exercisable within 60 days of .

(9) Includes (i) shares of common stock and (ii) shares of common stock that can be acquired pursuant to outstanding share options, including options that will be exercisable within 60 days of .

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, our outstanding warrant, the investors' rights agreement and of the General Corporation Law of the State of Delaware. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, warrant and investors' rights agreement, copies of which have been or will be filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the General Corporation Law of the State of Delaware. The description of our common stock and preferred stock reflects changes to our capital structure that will occur immediately prior the closing of this offering.

Following the closing of this offering, our authorized capital stock will consist of shares of common stock, par value $0.001 per share, and shares of preferred stock, par value $0.001 per share.

As of , 2021, there were shares of our common stock outstanding (including shares of unvested restricted stock) and shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock in connection with this offering, held of record by stockholders.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation. See below under "—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions." Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Warrants

In connection with entering into our loan and security agreement with Pacific Western Bank, as amended, we issued PacWest Bancorp a warrant to purchase 350,000 shares of Series A preferred stock at an exercise price of $0.50 per share. Upon the closing of this offering, the warrant will automatically become a warrant to purchase shares of our common stock at an exercise price of $ per share. The warrant expires on March 9, 2028.

Options

As of , 2021, options to purchase shares of our common stock were outstanding under our 2017 Plan, of which were exercisable and of which were unvested as of that date.

Registration Rights

Holders of shares of our common stock are entitled to certain rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to a Second Amended and Restated Investors' Rights Agreement, or the Investors' Rights Agreement, by and among us and certain of our stockholders, until the rights otherwise terminate pursuant to the terms of the Investors' Rights Agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Form S-1 Registration Rights

If at any time beginning 180 days after the closing date of this offering the holders of registrable securities request in writing that we effect a registration with respect to all or part of such registrable securities then outstanding and having an anticipated aggregate offering price that would exceed $10,000,000, net of expenses, we may be required to register their shares. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Piggyback Registration Rights

If at any time after this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Form S-3 Registration Rights

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of at least 30% of the registrable securities request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least $5,000,000, we will be required to effect such registration; provided, however, that we will not be required to effect such a registration if, within any twelve month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

Expenses and Indemnification

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration, filing and qualification fees, printers' and accounting fees, fees and disbursements of our counsel and reasonable fees and disbursements of a counsel for the selling securityholders. Additionally, we have agreed to indemnify selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement or alleged untrue statement of a material fact contained in any registration statement, an omission or alleged omission to state a material fact required to be stated in any registration statement, or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

Termination of Registration Rights

The registration rights terminate upon the earlier of (i) five years after the effective date of the registration statement relating to our IPO, (ii) immediately before the closing of a deemed liquidation event, as defined in our current certificate of incorporation and (iii) at such time after consummation of our IPO as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holders' shares without limitation during a three-month period without registration, or if any holder is an affiliate of the Company immediately after the consummation of our IPO, at such time as such holder is no longer an affiliate of the Company.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to

acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see “Management—Board Composition and Election of Directors.” This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act, or to any claim for which the federal courts have exclusive jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, Exchange Act, or the rules and regulations thereunder. Our restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be .

Stock Exchange Listing

We intend to apply to have our common stock listed on The Nasdaq Global Market under the symbol “OMGA.”

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of shares of common stock, assuming the issuance of shares of common stock offered by us in this offering, the automatic conversion of all outstanding shares of our preferred stock into shares of our common stock and no exercise of options or warrants after , 2021. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales will be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately shares will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

In addition, of the shares of our common stock that were subject to stock options outstanding as of , 2021, options to purchase shares of common stock were vested as of , 2021 and, upon exercise, these shares will be eligible for sale subject to the lock–up agreements described below and Rules 144 and 701 under the Securities Act, as applicable.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed that, without the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC and Piper Sandler & Co., we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock; or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

Upon the expiration of the applicable lock-up periods, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see "Underwriting."

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the

90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume in our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

Registration Rights

Upon the closing of this offering, the holders of shares of common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our preferred stock upon the closing of this offering, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION

OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30)

of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying any dividends in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below regarding effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaties.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest ("USRPI") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the Non-U.S. Holder certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN,

W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds from the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above or the Non-U.S. Holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting. Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act ("FATCA")) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock beginning on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Jefferies LLC and Piper Sandler & Co. are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	
Jefferies LLC	
Piper Sandler & Co.	
Wedbush Securities Inc.	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to additional shares from us.

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms.

The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make internet distributions on the same basis as other allocations.

We and our executive officers, directors, and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed or will agree with the

underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC and Piper Sandler & Co. See the section of this prospectus titled “Shares Eligible for Future Sale” for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol “OMGA.”

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $ million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively traded securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities or instruments of the issuer (directly, as collateral securing other obligations or otherwise) or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

European Economic Area

In relation to each Member State of the European Economic Area (each, a “Member State”), no offer of shares of our common stock may be made to the public in that Member State other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the representatives and us that it is a “qualified investor” as defined in the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5 of the Prospectus Regulation, each such financial intermediary will be deemed to have represented,

acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a nondiscretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Member State means the communication in any form and by means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase shares, the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

In the United Kingdom, this prospectus is only addressed to and directed at qualified investors who are (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order); or (ii) high net worth entities and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Any investment or investment activity to which this prospectus relates is available only to relevant persons and will only be engaged in with relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The securities may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies

(Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or Securities and Futures Ordinance, or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the

transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the “Corporations Act”), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This offering document is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be

illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority, or FINMA, as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended, or CISA, and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licensable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The securities may solely be offered to "qualified investors," as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended, or CISO, such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Goodwin Procter LLP. Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm own shares of our convertible preferred stock which will be converted into less than 1% of our common stock prior to the completion of this offering.

EXPERTS

The financial statements as of December 31, 2020 and 2019 and for the years then ended included in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to our ability to continue as a going concern). Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the SEC's website referred to above. We also maintain a website at www.omegatherapeutics.com, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus or the registration statement of which it forms a part, and the inclusion of our website address in this prospectus is an inactive textual reference only.

INDEX TO 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 balance sheet of Omega Therapeutics, Inc. (the "Company") as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2020 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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 evaluation of events and conditions and 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. Our opinion is not modified with respect to this matter.

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 and in accordance with auditing standards generally accepted in the United States of America. 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
May 7, 2021

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

Omega Therapeutics, Inc.
Balance sheets

(in thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 22,951	$ 2,274
Prepaid expenses and other current assets	1,052	380
Total current assets	24,003	2,654
Property and equipment, net	3,482	2,833
Restricted cash	341	341
Other assets	257	292
Total assets	$ 28,083	$ 6,120
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,063	$ 917
Accrued expenses	3,277	1,145
Other current liabilities	359	165
Long-term debt, current portion	3,000	—
Total current liabilities	7,699	2,227
Long-term debt, net	8,732	11,892
Other liabilities	1,055	1,212
Total liabilities	17,486	15,331
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, par value of $0.001 per share; 57,125,232 shares authorized; 56,775,232 shares issued and outstanding as of December 31, 2020 and 2019; liquidation value of $25,500 as of December 31, 2020 and 2019	26,708	26,708
Series B redeemable convertible preferred stock, par value of $0.001 per share; 50,000,000 shares authorized as of December 31, 2020; 32,399,999 shares issued and outstanding as of December 31, 2020; liquidation value of $48,600 as of December 31, 2020	48,517	—
Stockholders' deficit:		
Common stock, $0.001 par value; 137,700,000 and 81,150,000 shares authorized as of December 31, 2020 and 2019, respectively; 16,869,171 and 14,262,230 issued and outstanding as of December 31, 2020 and 2019, respectively	17	16
Additional paid-in capital	1,580	843
Accumulated deficit	(66,225)	(36,778)
Total stockholders' deficit	(64,628)	(35,919)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 28,083	$ 6,120

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

Omega Therapeutics, Inc.
Statements of operations and comprehensive loss

(in thousands, except share and per share amounts)

	Year ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 21,063	$ 11,931
General and administrative	6,236	4,227
Related party expense, net	1,346	1,181
Total operating expenses	28,645	17,339
Loss from operations	(28,645)	(17,339)
Other expense, net:		
Interest expense, net	(777)	(595)
Other expense, net	(25)	(11)
Total other expense, net	(802)	(606)
Net loss and comprehensive loss	$ (29,447)	$ (17,945)
Net loss per common stock attributable to common stockholders, basic and diluted	$ (2.00)	$ (1.43)
Weighted-average common stock used in net loss per share attributable to common stockholders, basic and diluted	14,756,671	12,538,575

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

Omega Therapeutics, Inc.
Statements of redeemable convertible preferred stock and stockholders' deficit

(in thousands, except share amounts)

	PREFERRED STOCK - SERIES A		PREFERRED STOCK - SERIES B		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' DEFICIT
	SHARES	PAR VALUE	SHARES	PAR VALUE	SHARES	PAR VALUE			
As of January 1, 2019	40,775,232	$ 18,732	—	$ —	12,192,592	$ 16	$ 484	$ (18,833)	$ (18,333)
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of $24	16,000,000	7,976	—	—	—	—	—	—	—
Issuance of common stock for options exercised	—	—	—	—	194,638	—	24	—	24
Vesting of restricted stock	—	—	—	—	1,875,000	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	335	—	335
Net loss	—	—	—	—	—	—	—	(17,945)	(17,945)
As of December 31, 2019	56,775,232	$ 26,708	—	$ —	14,262,230	$ 16	$ 843	$ (36,778)	$ (35,919)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $83	—	—	32,399,999	48,517	—	—	—	—	—
Issuance of common stock for options exercised	—	—	—	—	741,628	1	101	—	102
Vesting of restricted stock	—	—	—	—	1,875,000	—	—	—	—
Common stock repurchased	—	—	—	—	(9,687)	—	(1)	—	(1)
Stock-based compensation	—	—	—	—	—	—	637	—	637
Net loss	—	—	—	—	—	—	—	(29,447)	(29,447)
As of December 31, 2020	56,775,232	$ 26,708	32,399,999	$ 48,517	16,869,171	$ 17	$ 1,580	$ (66,225)	$ (64,628)

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

Omega Therapeutics, Inc.
Statements of cash flows

(in thousands)

	Year ended December 31, 2020	2019
Operating activities		
Net loss	$ (29,447)	$ (17,945)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,146	794
Amortization of debt issuance costs and debt discount	48	36
Change in fair value of warrant liability	(3)	(3)
Stock-based compensation expense	637	335
Deferred rent	(107)	(77)
Loss on disposal of equipment	28	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(663)	(244)
Other assets	35	23
Accounts payable	138	671
Accrued expenses and other current liabilities	2,295	754
Other liabilities	(240)	(23)
Net cash used in operating activities	(26,133)	(15,679)
Investing activities		
Purchases of property and equipment	(1,808)	(885)
Net cash used in investing activities	(1,808)	(885)
Financing activities		
Proceeds from issuance of redeemable convertible preferred stock	48,600	8,000
Equity issuance costs	(83)	(24)
Proceeds from issuances of long-term debt	—	4,000
Payment of financing fees	—	(15)
Proceeds from exercise of stock options	101	24
Net cash provided by financing activities	48,618	11,985
Net increase (decrease) in cash, cash equivalents and restricted cash	20,677	(4,579)
Cash, cash equivalents and restricted cash—beginning of period	2,615	7,194
Cash, cash equivalents and restricted cash—end of period	$ 23,292	$ 2,615
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 22,951	$ 2,274
Restricted cash	341	341
Cash, cash equivalents and restricted cash	$ 23,292	$ 2,615
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 732	$ 560
Supplemental disclosure of noncash investing and financing activities		
Purchase of property and equipment included accounts payable and accrued expenses	$ 23	$ 4
Fair value attributed to success fee obligation	$ 194	$ —

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

Omega Therapeutics, Inc.
Notes to financial statements

1. Nature of the business and basis of presentation

Organization

Omega Therapeutics, Inc. (the “Company” or “Omega”) is a development-stage biopharmaceutical company. The Company’s goal is to pioneer a new class of DNA-sequence-targeting, mRNA-encoded therapeutics to fundamentally transform human medicine in the service of patients. Its OMEGA Epigenomic Programming platform is designed to coopt nature’s universal operating system by harnessing the power of epigenetics, the mechanism for gene control and cell differentiation. The Company was incorporated in July 2016 (“inception”) as a Delaware corporation and its offices are in Cambridge, Massachusetts.

Liquidity and going concern

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

As presented in the financial statements, the Company has incurred substantial losses since inception and had a net loss of $29.4 million for the year ended December 31, 2020. As of December 31, 2020, the Company had an accumulated deficit of $66.2 million, with cash used in operating activities totaling $26.1 million for the year ended December 31, 2020. The Company expects to generate operating losses and negative operating cash flows for the foreseeable future.

Management believes that cash and cash equivalents of $23.0 million at December 31, 2020, along with the additional funding subsequent to December 31, 2020 from the issuance of Series C redeemable convertible preferred stock (“Series C Preferred Stock”) of aggregate proceeds of $125.5 million as described in Note 17, *Subsequent events*, will not be sufficient to fund its operations for twelve months from the date these financial statements are issued. If the Company cannot obtain the necessary funding, it will need to delay, scale back or eliminate some or all of its research and development programs; consider other various strategic alternatives, including a merger or sale of the Company; or cease operations. The Company currently has no sources of revenue and its ability to continue as a going concern is dependent on its ability to raise capital to fund its future business plans. Additionally, volatility in the capital markets and general economic conditions in the United States may be a significant obstacle to raising the required funds. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties. Accordingly, the 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.

Impact of the COVID-19 pandemic

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

The Company is following, and plans to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. In response to the direction from state and local governmental authorities, the Company has restricted access to its facility to those individuals who must perform critical research and laboratory support activities that must be completed on site, limited the number of such people that can be present at its facility at any one time and required that most of its employees work remotely. In addition, the third-party contract research organizations and contract manufacturing organizations that the Company engages have faced in the past and may face in the future disruptions that could affect its ability to initiate and complete preclinical studies, including disruptions in procuring items that are essential for its research and development activities, such as, for example, raw materials used in the manufacture of its product candidates and laboratory supplies for its preclinical studies, in each case, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business, and the pandemic has the potential to adversely affect the Company's business, financial condition, results of operations and prospects.

Basis of presentation

The accompanying 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

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances.

Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the selection of useful lives of property and equipment, the fair values of common stock, redeemable convertible preferred stock, warrants, and success fee obligation, and stock-based compensation. Actual results could differ from these estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents are recorded at cost, which

approximates fair value. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and the Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. As of December 31, 2020 and 2019, the Company did not hold any cash equivalents.

Restricted cash

Restricted cash represents collateral provided for letters of credit issued as security deposit in connection with the Company's office lease.

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.

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, 2020 and 2019, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related 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 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. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its 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 its prior estimates of accrued research and development expenses.

Warrant liability

Warrants for the purchase of Series A redeemable convertible preferred stock ("Series A Preferred Stock") issued in connection with the loan and security agreement ("Loan Agreement") with Pacific Western Bank ("PWB") are classified as a liability on the balance sheets at their fair value on the date of issuance. At the end of each reporting period, the change in estimated fair value during the period is recognized as a component of other income (expense), net in the statements of operations and comprehensive loss. The fair value of the warrants is remeasured at the end of each reporting period until such time as the warrants are no longer considered derivative instruments, or until the earlier of the exercise of the warrants or the expiration of the warrants, at which time the liabilities will be reclassified to an equity component.

Success fee obligation

The Loan Agreement, as amended, with PWB, requires the Company to pay a success fee of $0.2 million ("success fee obligation") upon the occurrence of a specified liquidity event as described in the Loan Agreement, such as a strategic sale, a merger, or an initial public offering ("IPO"). 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 balance sheets and initially recorded at fair value, with changes in fair value for each reporting period recognized in other income (expense), net in the statements of operations and comprehensive loss. The fair value of such obligation is remeasured at the end of each reporting period until the liability is settled.

Deferred rent

The Company's real estate operating leases provide for scheduled annual rent increases throughout the lease terms. The Company recognizes the effects of the scheduled rent increases on a straight-line basis over the full terms of the leases. Tenant improvement allowances, if any, provided by a landlord are recorded as deferred rent and amortized as reductions to rent expense over the lease terms.

Impairment of long-lived assets

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

Fair value measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an

orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The fair value of the Company's cash and cash equivalents and restricted cash are measured through quoted market prices. Other current assets, accounts payable and accrued liabilities approximate their fair values as of December 31, 2020 and 2019, due to their short-term nature. The carrying value of the Company's debt approximates its fair value due to its variable interest rate, which approximates a market interest rate. The warrant liability and the success fee obligation associated with the Loan Agreement contain unobservable inputs that reflect the Company's own assumptions in which there is little, if any, market activity at the measurement date, thus the Company's warrant liability and the success fee obligation are measured at their fair values on a recurring basis using unobservable inputs. See further discussion in Note 7, *Fair value of financial instruments*.

Redeemable convertible preferred stock

The Company has classified redeemable convertible preferred stock as temporary equity on the accompanying balance sheets because it could become redeemable upon occurrence of a deemed liquidation event that is outside of the Company's control. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to its redemption value because it is uncertain whether or when a deemed liquidation event would occur. If a deemed liquidation event becomes probable, the carrying value will be adjusted to the redemption value at that time. See further discussion in Note 10, *Redeemable convertible preferred stock*.

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 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 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 stock options and restricted stock awards. Stock-based compensation awards are granted to employees and non-employees.

The Company recognizes all stock-based compensation awards to employees and non-employees as expense in the 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. Prior to the adoption of ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07") as discussed below under "Recently Adopted Accounting Pronouncements", the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. Since the adoption of ASU 2018-07 as of January 1, 2020, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. 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 and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees and non-employees, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Due to the absence of an active market during the years ended December 31, 2020 and 2019 for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately- Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

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 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, 2020 and 2019, 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

The Company did not have any other comprehensive income or loss for any periods presented and, therefore comprehensive loss did not differ from net loss.

Net loss per share

The Company follows the two-class method when computing net loss per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2020 and 2019.

Segment and geographic information

Operating segments are defined as components of an entity about which discrete information is available for evaluation by the chief operating decision maker, or CODM, or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company's Chief Executive Officer. The CODM views its operations as and manages its business in one operating segment operating exclusively in the United States.

Recently issued accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. As the Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jumpstart Our Business Startups Act ("JOBS Act"), the standard is effective for the Company beginning January 1, 2022, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes-Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes, enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. Adoption of the standard requires certain changes to be made prospectively and certain others to be made retrospectively. As the Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the JOBS Act, the standard is effective for the Company beginning January 1, 2022, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2019-12 will have on its financial statements.

Recently adopted accounting pronouncements

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 aims to simplify the accounting for share-based payments to nonemployees by aligning it to the accounting for share-based payments to employees including determining the fair value of the award on the date of grant and recognizing the stock-based compensation expense as of the respective vesting date. The new standard also requires companies to elect to either measure the awards to non-employees over an estimated expected term or contractual term as well as elect to estimate forfeitures or account for forfeitures as they occur. ASU 2018-07 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019 and is to be adopted using a modified retrospective approach with a cumulative catch-up to retained earnings recorded for equity-classified awards for which a measurement date has not been established as of the date of adoption. The Company adopted ASU 2018-07 effective January 1, 2020, and the adoption of the new standard did not have a material impact on the Company's financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement* ("ASU

2018-13"), which changes the disclosure requirements on fair value measurements in Topic 820. The guidance eliminates certain disclosure requirements that are no longer considered cost beneficial and adds new disclosure requirement for Level 3 fair value measurements. The Company adopted ASU 2018-13 effective January 1, 2020, and the adoption of the new standard did not have a material impact on the Company's financial statements and related disclosures.

3. Prepaid expenses and other current assets

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

	December 31,	
	2020	2019
Prepaid rent	$ —	$170
Prepaid software	78	96
Prepaid research and development	653	—
Prepaid other	128	109
Other receivables	193	5
Prepaid expenses and other current assets	$1,052	$380

4. Property and equipment, net

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

	December 31,	
	2020	2019
Leasehold improvements	$ 1,378	$ 1,202
Lab equipment	3,444	2,745
Furniture and fixtures	985	187
Computer equipment	129	90
Construction in process	16	—
Total property and equipment	5,952	4,224
Less accumulated depreciation	(2,470)	(1,391)
Property and equipment, net	$ 3,482	$ 2,833

Depreciation expense for the years ended December 31, 2020 and 2019 was $1.1 million and $0.8 million, respectively.

5. Accrued expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2020	2019
Employee related expenses	$1,124	$ 746
Research costs	1,724	141
Consulting fees	165	156
Interest	44	44
Other	220	58
Total	$3,277	$1,145

6. Term Loan

On March 9, 2018 (“Closing Date”), the Company entered into the Loan Agreement with PWB, a California state-chartered bank. Under the Loan Agreement, the Company may borrow amounts not to exceed $8.0 million, which consisted of Tranche I and Tranche II, with the Tranche I funded on the Closing Date and Tranche II funded no later than 18 months from the Closing Date. The Company borrowed $3.5 million under Tranche I on the Closing Date and $4.5 million under Tranche II in August 2018, and the full amount of $8.0 million was to be repaid beginning 18 months from the Closing Date in thirty equal installments, including interest at a floating annual rate equal to the greater of (i) 0.75% above the prime rate then in effect and (ii) 5.00%, due monthly starting the first month after the Closing Date.

In conjunction with the Loan Agreement, under Tranche I, the Company issued a warrant to PWB to purchase 87,500 shares of Series A Preferred Stock at the initial strike price of $0.50 per share. The warrant is exercisable for a 10-year period. Additionally, the warrant shall be exercisable for an additional number of shares of Series A Preferred Stock equal to the amount borrowed under Tranche II multiplied by 0.0125. In no event shall the warrant be exercisable for more than 200,000 shares of Series A Preferred Stock. Upon closing of Tranche II, the warrant was not exercised for additional number of shares of Series A Preferred Stock. In lieu of exercising the warrant, PWB may, in whole or in part, convert the warrant into a number of shares of Series A Preferred Stock, determined by (a) dividing the aggregate fair market value of the Series A Preferred Stock shares minus the aggregate warrant price of such shares by (b) the fair market value of one share of Series A Preferred Stock. The fair market value of the Series A Preferred Stock shares shall be determined based upon either the publicly traded closing price on the date of the conversion or, if not publicly traded, a value deemed appropriate by the Company’s board of directors. Refer to Note 7, *Fair value of financial instruments*, for further discussion on the valuation methodology and inputs for the determination of the fair value of the warrants.

On September 30, 2019, the Company entered into an amendment to the Loan Agreement (the “First Amendment”), in which PWB made an additional term loan pursuant to a new Tranche III to the Company in an aggregate principal amount of $12.0 million. The proceeds of the term loan pursuant to Tranche III were first applied to the repayment in full of all outstanding principal and accrued interest on the outstanding term loan of $8.0 million borrowed pursuant to Tranche I and Tranche II; the remaining cash proceeds of $4.0 million was used for general working capital and for capital expenditures purposes. The maturity date of the additional term loan was initially March 9, 2022, and it would have been repaid beginning on January 9, 2020 in twenty-seven equal installments. However, the first closing of the Company’s Series B Preferred Stock financing in January 2020 satisfied the cash proceeds milestone noted in the First Amendment, in which the maturity date of the amended term loan was extended to June 9, 2023, and the term loan was to be repaid beginning in January 2021 in thirty equal installments, including interest at a floating annual rate equal to the greater of (i) 0.75% above the prime rate then in effect and (ii) 6.00%, due monthly starting the first month after September 30, 2019. The Company incurred $15 thousand of debt issuance costs, which was recorded as a direct reduction against the additional term loan and amortized over the life of the associated term loan as a component of interest expense using the effective interest method.

In conjunction with the First Amendment, the Company also issued a warrant to purchase 350,000 shares of Series A Preferred Stock, which effectively restated and replaced the original warrant agreement. The strike price of the amended warrant is $0.50 per share, and the term remains unchanged, expiring in March 2028. No warrants have been exercised to date. Refer to Note 7, *Fair value of financial instruments*, for further discussion on the valuation methodology and inputs for the determination of the fair value of the warrants.

As the warrants issued are freestanding financial instruments that are exercisable for contingently redeemable shares, they were initially recorded at fair value on the date of issuance as a liability, with

a corresponding discount recorded against the face value of the term loan. The discount was accreted against the face value of the term loan over its remaining term as additional interest expense. At the end of each reporting period, the change in estimated fair value of the warrants during the period is recognized as a component of other income (expense), net in the statements of operations and comprehensive loss.

On January 22, 2020, the Loan Agreement was further amended (the "Second Amendment") to extend the principal repayment start date, from January 9, 2020 as noted in the First Amendment to February 9, 2020; the number of repayment installments was also amended from twenty-seven equal installments to twenty-six equal installments. No additional proceeds were taken under the Second Amendment, and there were no other material amendments to the terms and conditions.

On December 30, 2020, the Loan Agreement was further amended (the "Third Amendment") to extend the principal repayment date. No additional proceeds were taken under the Third Amendment. The maturity date of the term loan was extended to June 30, 2023, and it is to be repaid beginning on June 30, 2021 in twenty-four equal installments, including interest at a floating annual rate equal to the greater of (i) 0.75% above the prime rate then in effect and (ii) 6.00%, due monthly starting the first month after December 30, 2020. The Company incurred $15 thousand of debt issuance costs, which have been recorded as a direct reduction against the term loan and amortized over the life of the associated term loan as a component of interest expense using the effective interest method.

In accordance with the Third Amendment, in the event that the Company has satisfied the cash proceeds milestone, as defined in the Third Amendment, the principal repayment date will be extended to December 31, 2021 and the maturity date will be extended to December 31, 2023. Additionally, the Company is required to pay a success fee of $0.2 million upon the occurrence of a specified liquidity event, as described in the Loan Agreement, which includes an IPO. The Company determined that this obligation represented a freestanding financial instrument. Accordingly, the success fee obligation was classified as a liability on the Company's balance sheet and initially recorded at fair value, with changes in fair value for each reporting period recognized in other income (expense), net in the statement 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.

As of December 31, 2020, the long-term debt, current portion was $3.0 million, and the long-term debt was $9.0 million. The Company's outstanding term loan balance was comprised of the following (in thousands):

	December 31,	
	2020	2019
Principal	$12,000	$12,000
Unamortized debt discount	(268)	(108)
Net carrying amount	$11,732	$11,892

The Company determined that the expected life of the debt was equal to the term on the term loan. The effective interest rate on the liability component ranged from 5.53% to 7.51% for the period from the date of issuance through December 31, 2020. The following table sets forth total interest expense recognized related to the term loan (in thousands):

	Year ended December 31,	
	2020	2019
Contractual interest expense	$ 732	$ 559
Amortization of debt issuance costs and debt discount	48	36
Total interest expense	$ 780	$ 595

As of December 31, 2020 and 2019, accrued interest on the term loan was $44 thousand.

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

2021	3,000
2022	6,000
2023	3,000
	$12,000

7. Fair value of financial instruments

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

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Financial Liabilities				
Warrant liability	$ —	$ —	$ 124	$124
Success fee obligation	—	—	194	194
Total	$ —	$ —	$ 318	$318

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Financial Liabilities				
Warrant liability	$ —	$ —	$ 127	$127

The Company's warrant liability and success fee obligation contain unobservable inputs that reflected the Company's own assumptions in which there is little, if any, market activity at the measurement date. Accordingly, the Company's warrant liability and success fee obligation are measured at fair value on a recurring basis using unobservable inputs at each reporting period and are classified as Level 3 inputs. The warrant liability is shown as non-current liabilities on the balance sheets as they are deemed more probable than not by the Company to be settled in longer than one year.

The fair values of the warrants are estimated using the Black-Scholes option-pricing model. The expected terms represent the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants.

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

	Year ended December 31,	
	2020	2019
Expected volatility	73.09 - 77.79%	72.45 - 73.58%
Risk-free interest rate	0.58 -0.65%	1.65 -1.88%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	7.2 - 7.9	8.2 - 8.5

The fair value of the warrants will be remeasured at each reporting period, with changes in fair value recognized in the statements of operations and comprehensive loss. The changes in the fair value of the warrant liability during the years ended December 31, 2020 and 2019 are immaterial.

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 include the probability of achieving a specified liquidity event, the expected timing of achieving a liquidity event and discount rate. The fair value of the success fee obligation is remeasured at each reporting period, with changes in fair value recognized in the statement of operations and comprehensive loss, until such liability is settled. The success fee obligation is recorded as current liabilities on the balance sheet as it is deemed more probable than not by the Company to be settled in less than one year.

The following reflects the significant quantitative inputs used to determine the valuation of the success fee obligation upon the amendment of the Loan Agreement executed in December 2020:

Discount rate	6.0%
Expected timing of achieving liquidity events (years)	0.5 - 1
Probability of achieving liquidity events	1% - 99%

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

	Warrant liability	Success fee obligation
Fair value as of January 1, 2019	$ 76	$ —
Issuance of warrant	54	—
Change in fair value	(3)	—
Fair value as of December 31, 2019	127	—
Initial fair value of success fee obligation	—	194
Change in fair value	(3)	—
Fair value as of December 31, 2020	$ 124	$ 194

8. Commitments and contingencies

Operating leases

In 2017, the Company entered a noncancelable operating lease agreement to lease its office space in Cambridge, Massachusetts, which will expire in September 2024. The Company is required to pay property taxes, insurance, and normal maintenance costs. The operating lease contains predetermined fixed escalations of minimum rentals during the lease term. During 2018, the Company received $1.1 million of landlord-funded leasehold improvements related to the leased office space. The landlord-funded leasehold improvements were recorded as property and equipment, net and deferred rent in the balance sheets and

are being amortized as a reduction to rent expense over the life of the lease. In 2019 and 2020, the Company entered into sublease agreements with two related parties to sublease this office and laboratory space. Refer to Note 15, *Related party transactions*, for further details.

On July 13, 2020, the Company entered into a Shared Space Arrangement ("the Arrangement") with Senda Biosciences ("Senda", also formerly known as Kintai Therapeutics, Inc.) to share one-third of Senda's 69,867 square feet of leased space at 20 Acorn Park Drive, Cambridge, Massachusetts. Senda is a related party as it is an affiliate of Flagship Pioneering ("Flagship"). The Arrangement commenced on August 1, 2020 and continues through July 31, 2022 with two options to extend the term of the Arrangement for a period of 24 months each. The operating lease contains predetermined fixed escalations of minimum rentals during the lease term, and the Company is required to pay property taxes, insurance, and normal maintenance costs. During the year ended December 31, 2020, the Company paid Senda $1.0 million for rental expenses, in addition to $0.7 million of reimbursement for office furniture purchases. As of December 31, 2020, the Company did not have any outstanding payments due to Senda.

The Company recognizes the rental expense on a straight-line basis over the life of the respective lease from the date the Company takes possession of the office and records the difference between amounts charged to operations and amounts paid as deferred rent. Rent expense for the years ended December 31, 2020 and 2019 was $2.2 million and $1.3 million, respectively.

As of December 31, 2020, the future minimum lease payments for the Company's facility operating leases for each of the years ending December 31 were as follows (in thousands):

2021	3,322
2022	2,618
2023	1,563
2024	1,205
Total minimum lease payments	$8,708

9. 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 one of the Company's principal stockholders, 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 license 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, which was recorded as an expense for the year ended December 31, 2019. 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, which was recorded as an expense for the year ended December 31, 2019. The Company is obligated to pay WIBR annual license maintenance fees of less than $0.1 million and sub single digit percentage royalties on net sales of licensed products by the Company and its affiliates and sublicensees as well as low single digit percentage royalties on licensed service income received by the Company and its affiliates. Additionally, the Company is required to make milestone payments of up to $1.9 million in the aggregate for each of the first three licensed products (excluding backup products) upon the achievement of specified clinical, regulatory, and sublicensing milestones. In addition, the Company is required to pay to WIBR annual fees of less than $0.1 million for each sublicense agreement.

During the years ended December 31, 2020 and 2019, the Company recognized expenses of less than $0.1 million for the license maintenance fees and $0.1 million for the upfront fee payments, respectively. There was no outstanding payment due to WIBR as of December 31, 2020, and an immaterial amount of outstanding payment was due to WIBR as of December 31, 2019.

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. As the triggering of these milestone payments was not considered probable during 2020 and 2019, no expense has been recorded for these milestones during the years ended December 31, 2020 and 2019. Lastly, the royalty payments and the sublicense non-royalty payments are contingent upon sales of license products or execution of a sublicence 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 sublicence 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’s . Additionally, in accordance with the Development and Option Agreement, the Company has options to obtain non-exclusive, worldwide, sublicensable licenses under Acuitas’s patents and know-how related to lipid nanoparticle

technology (“Acuitas LNP Technology”) with respect to two specified targets (e.g., OEC constructs) (“Reserved Targets”) to develop and commercialize one or more therapeutic products relating to such targets. For each option and Reserved Target, the Company is obligated to pay an annual technology access fee and target reservation and maintenance fees collectively in the low-mid six figures until such Reserve Targets 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 FTE funding obligations and reimbursements to Acuitas for certain development and material costs incurred by them, which is currently approximately $0.4 million per year.

During the year ended December 31, 2020, the Company recorded an aggregate of $0.8 million of research and development expenses, consisting of the payments made for technology access fees, target reservation and maintenance fees, and the development and material costs incurred by Acuitas.

The option exercise fees under the Development and Option Agreement will be recorded as research and development expense, if and when the Company exercises such options. 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.

10. Redeemable convertible preferred stock

Series A Redeemable Convertible Preferred Stock

On August 4, 2017, the Company entered into a Series A Preferred Stock Purchase Agreement (“Series A Agreement”) with certain investors (the “Purchasers”). Under the Series A Agreement, the Company issued an aggregate of 13,000,000 shares (the “Initial Shares”) of Series A Preferred Stock at a purchase price of $0.50 per share for aggregate proceeds of $6.5 million. In addition, promissory notes were issued by the Company in the aggregate principal amount of $2.8 million plus $54 thousand in accrued interest (collectively, the “Bridge Notes”), which were exchanged for an aggregate of 5,775,232 shares of Series A Preferred Stock (the “Conversion Shares”). The Company incurred issuance costs of $15 thousand in connection with the issuance of the Initial Shares.

The Series A Agreement also includes rights for each Purchaser to purchase additional Series A Preferred Stock upon the achievement of certain milestone events, in which the Company met in 2018 and therefore issued additional 22,000,000 shares of Series A Preferred Stock, at the Series A purchase price of $0.50 per share for aggregate proceeds of $11.0 million. On June 27, 2018, the Company amended the Amended and Restated Certificate of Incorporation to authorize the issuance of an additional 200,000 shares of Series A Preferred Stock for a total of 40,975,232 authorized shares of Series A Preferred Stock. In connection with the issuance of the additional Series A Preferred Stock in 2018, the Company incurred $7 thousand of issuance costs.

On June 10, 2019, the Company amended the Amended and Restated Certificate of Incorporation to authorize the issuance of an additional Series A Preferred Stock for a total of 56,975,232 authorized shares of Series A Preferred Stock. Simultaneously, in June 2019, the Company issued the additional 16,000,000 shares of Series A Preferred Stock, at the Series A purchase price of $0.50 per share for aggregate proceeds of $8.0 million. In connection with the issuance of Series A Preferred Stock in 2019, the Company incurred $24 thousand of issuance costs. On October 1, 2019, the Company further amended the Amended and Restated Certificate of Incorporation to authorize the issuance of an additional 150,000 shares of both common stock and Series A Preferred Stock for a total of 81,150,000 authorized shares of common stock and 57,125,232 authorized shares of Series A Preferred Stock.

No additional shares were issued under the Series A Preferred Stock Purchase Agreement after June 2019.

Series B Redeemable Convertible Preferred Stock

On January 27, 2020, the Company issued 24,066,666 shares of Series B redeemable convertible preferred stock ("Series B Preferred Stock") at a purchase price of $1.50 per share for aggregate proceeds of $36.1 million. On June 2, 2020, the Company issued an additional 3,333,333 shares of Series B Preferred Stock at the purchase price of $1.50 per share for aggregate proceeds of $5.0 million. On August 3, 2020, the Company issued 5,000,000 shares of Series B Preferred Stock at the purchase price of $1.50 per share for aggregate proceeds of $7.5 million. No additional shares of Series B Preferred Stock were issued after August 2020. In connection with the issuance of Series B Preferred Stock in 2020, the Company incurred $83 thousand of issuance costs.

The redeemable convertible preferred stock consisted of the following (in thousands, except for share data):

	December 31, 2020				
	Preferred Stock Authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A Preferred Stock	57,125,232	56,775,232	$ 26,708	$ 25,500	56,775,232
Series B Preferred Stock	50,000,000	32,399,999	48,517	48,600	32,399,999
	107,125,232	89,175,231	$ 75,225	$ 74,100	89,175,231

	December 31, 2019				
	Preferred Stock Authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A Preferred Stock	57,125,232	56,775,232	$ 26,708	$ 25,500	56,775,232

The following is a summary of the rights and preferences of the Series A and Series B Preferred Stock (collectively the "Preferred Stock") as of December 31, 2020 and 2019:

Conversion— Each share of Preferred Stock is convertible, at the option of the holder into an equal amount of fully paid and non-assessable shares of common stock as is determined by dividing the respective original Preferred Stock issue price by the respective Preferred Stock Conversion Price in effect at the time of conversion. The Series A and Series B Conversion Price are $0.50 and $1.50, respectively, subject to appropriate adjustment as set forth in the Company's Amended and Restated Certificate of Incorporation, as amended and restated. As such, the shares of Preferred Stock currently convert on a one-for-one basis. No fractional shares of common stock will be issued.

Upon either (a) the closing of the sale of shares of common stock, in a firm-commitment underwritten public offering with at least $35,000,000 of gross proceeds to the Company or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority in voting power of the then-outstanding shares of Preferred Stock, then (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of common stock, at the applicable conversion ratio then in effect, and (ii) such shares may not be reissued by the Company.

Dividends— The holders of Preferred Stock are entitled to receive noncumulative dividends if and when declared by the Company's board of directors. The Company may not declare, pay or set aside any dividends on shares of any other series of capital stock of the Company, other than

dividends on common stock payable in common stock, unless the holders of the Preferred Stock first receive, or simultaneously receive, a dividend on each outstanding share of Series A and Series B Preferred Stock. No dividends were declared or paid during the years ended December 31, 2020 and 2019.

Voting Rights— The holders of Preferred Stock are entitled to vote, together with the holders of common stock as a single class, on matters submitted to stockholders for a vote. The holders of Preferred Stock are entitled to the number of votes equal to the number of shares of common stock into which each such share of Preferred Stock could convert.

Liquidation Preference— While the Preferred Stock is not redeemable at the option of the holders, the shares are redeemable for cash in certain change of control events that are beyond the control of the Company. In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, or deemed liquidation event (as described below), the holders of the Preferred Stock are entitled to receive a liquidation preference in priority over the holders of common stock, at an amount per share equal to the greater of i) the respective original Preferred Stock issue price plus any declared but unpaid dividends, or ii) the amount per share payable had all shares of Preferred Stock been converted to common stock immediately prior to such liquidation. If assets available for distribution are insufficient to satisfy the liquidation payment to holders in full, assets available for distribution will be allocated among holders based on their pro rata shareholdings. When holders are satisfied in full, any excess assets available for distribution will be allocated ratably among common stockholders based on their pro rata shareholdings.

Unless the holders of a majority of the then-outstanding shares of Preferred Stock, consenting or voting together as a single class, elect otherwise, a deemed liquidation event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

11.Common stock

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, 2020, the Company has reserved 56,775,232 and 32,399,999 shares of common stock for the potential conversion of Series A and Series B Preferred Stock, respectively, and 11,521,868 shares of common stock for the potential exercise of outstanding stock options under the 2017 Equity Incentive Plan (“2017 Plan”).

12.Equity incentive plan

2017 Equity Incentive Plan

In June 2017, the Company’s board of directors adopted the 2017 Plan, which provided for the grant of qualified incentive stock options and nonqualified stock options, restricted stock or other awards to the Company’s employees and non-employees for the issuance or purchase of shares of the

Company's common stock. As of December 31, 2019, the 2017 Plan allowed for the issuance of up to 7,300,000 shares of common stock, and it was amended to provide up 14,700,000 shares of common stock for the issuance of stock options and restricted stock in 2020. As of December 31, 2020, there were 2,108,961 shares of common stock available for future grant under the 2017 Plan.

The 2017 Plan is administered by the Company's board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common stock on the date of grant. Stock options awarded under the 2017 Plan expire 10 years after the grant date unless the board of directors sets a shorter term. Vesting periods for awards under the 2017 Plan are determined at the discretion of the board of directors. Incentive stock options 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.

For the years ended December 31, 2020 and 2019, the Company recorded stock-based compensation expense of $0.6 million and $0.3 million, respectively, allocated to research and development and general and administrative expenses in the statements of operations and comprehensive loss as follows (in thousands):

	Year ended December 31,	
	2020	2019
Research and development	$ 299	$ 251
General and administrative	338	84
Total stock-based compensation expense	$ 637	$ 335

Stock options

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

	Year ended December 31,	
	2020	2019
Expected volatility	72.44 - 79.02%	72.08 - 73.98%
Weighted-average risk-free interest rate	1.00%	1.91%
Expected dividend yield	0.00%	0.00%
Weighted-average expected term (in years)	5.91	6.11

A summary of option activity under the 2017 Plan during the year ended December 31, 2020 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 December 31, 2019	6,552,358	$ 0.14	9.38	$ 20
Granted	6,438,938	0.42		
Exercised	(741,628)	0.14		
Forfeitures	(727,800)	0.24		
Outstanding as of December 31, 2020	11,521,868	0.29	8.86	4,467
Vested and expected to vest as of December 31, 2020	11,521,868	0.29	8.86	4,467
Exercisable as of December 31, 2020	2,713,892	0.14	8.17	1,453

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money as of December 31, 2020 and 2019.

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2020 and 2019 was $0.28 and $0.09, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2020 and 2019 was $0.4 million and $3 thousand, respectively.

The aggregate grant date fair value of stock options vested during the years ended December 31, 2020 and 2019 were $0.3 million and $44 thousand, respectively.

As of December 31, 2020, there was $1.7 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 3.14 years.

Restricted stock

In 2017, the Company issued 7,500,000 shares of restricted common stock to certain scientific founders, having a fair value of $0.8 million, and subject to vesting over a period of 4 years.

If the holders of restricted common stock cease to have a business relationship with the Company prior to the vesting of such shares, the Company may reacquire any unvested shares of common stock held by these individuals for the original purchase price, and in certain instances for no consideration. The unvested shares of restricted common stock are not considered outstanding shares for accounting purposes until the shares vest.

A summary of the status of and change in unvested restricted stock as of December 31, 2020 was as follows:

	Shares	Weighted-average grant date fair value
Unvested as of December 31, 2019	1,875,000	$ 0.11
Issued	—	—
Vested	(1,875,000)	0.11
Unvested as of December 31, 2020	—	$ —

The aggregate fair value of restricted shares that vested during each of the years ended December 31, 2020 and 2019 was $0.2 million.

As the restricted stock was fully vested in 2020, there was no remaining unrecognized stock-based compensation expense related to restricted stock.

13. 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,	
	2020	2019
Numerator:		
Net loss attributable to common stockholders	$ (29,447)	$ (17,945)
Denominator:		
Weighted average number of common stock, basic and diluted	14,756,671	12,538,575
Net loss per common stock attributable to common stockholders, basic and diluted	$ (2.00)	$ (1.43)

The Company excluded the following potential common stock, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Year ended December 31,	
	2020	2019
Redeemable convertible preferred stock	89,175,231	56,775,232
Unvested restricted stock	—	1,875,000
Outstanding options to purchase common stock	11,521,868	6,552,358
Warrants	350,000	350,000
Total	101,047,099	65,552,590

14. 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,	
	2020	2019
U.S. federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	7.7	7.4
Research and development tax credits	2.8	2.0
Nondeductible/ nontaxable permanent items	(0.5)	(0.6)
Change in valuation allowance	(30.8)	(29.8)
Other	(0.2)	—
Effective income tax rate	0%	0%

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

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Net operating loss carryforwards	$ 17,320	$ 9,612
Research and development credit carryforwards	2,424	1,162
Accrued expenses	539	484
Stock-based compensation	9	11
Intangibles	167	182
Total deferred tax assets	20,459	11,451
Less: valuation allowance	(20,217)	(11,159)
Deferred tax assets, net	242	292
Deferred tax liabilities:		
Depreciation	(242)	(292)
Total deferred tax liabilities	(242)	(292)
Net deferred taxes	$ —	$ —

The Company had no income tax expense due to the operating loss incurred for the years ended December 31, 2020 and 2019. Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's net deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets. As a result, the Company has recorded a full valuation allowance as of December 31, 2020 and 2019. The valuation allowance increased by $9.1 million in 2020, due to the increase in deferred tax assets, primarily resulting from the net operating loss carryforwards, research and development tax credits, 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, 2020, the Company had $63.6 million of federal and $62.6 million of state net operating loss carryforwards. If not utilized, both the federal and state net operating loss carryforwards have components that begin to expire starting in 2036. Of the $63.6 million federal net operating loss carryforwards, $58.1 million of net operating loss generated from 2018 to 2020 will not expire. Additionally, as of December 31, 2020, the Company had $1.4 million of federal and $1.3 million of Massachusetts tax credits that expire starting in 2036 and 2031, respectively.

As of December 31, 2019, the Company had $35.2 million of federal and $34.9 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. Included in the $35.2 million federal net operating loss carryforwards is $29.8 million of net operating loss generated in 2018 and 2019 that will

not expire. Additionally, as of December 31, 2019, the Company had $0.6 million of federal and $0.7 million of Massachusetts tax credits that will expire starting in 2036 and 2031, respectively.

As of December 31, 2020 and 2019, the Company had no uncertain tax positions. The Company will recognize both interest and penalties associated with unrecognized tax benefits as a component of income tax expense. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception.

The Company filed income tax returns in the United States and the Commonwealth of Massachusetts in all tax years since inception. The tax years 2019 and 2018 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.

15. Related party transactions

The majority ownership of the Company is held by Flagship. Fully diluted Flagship ownership was 70.9% and 81.1% as of December 31, 2020 and 2019, respectively. Flagship provides management services (accounting, human resources, information technology, legal and consultation) to the Company. Flagship is also reimbursed for certain expenses, including insurance and benefits, partner and related fees, and software licenses incurred on the Company's behalf. For the years ended December 31, 2020 and 2019, the Company incurred $0.9 million and $1.1 million, respectively, for the management services fees and other reimbursements that Flagship incurred on the Company's behalf. These expenses are recorded as related party expense in the accompanying statements of operations and comprehensive loss. As of December 31, 2020 and 2019, the Company did not have any outstanding payments due to Flagship.

In September 2020, the Company sublet the entire space of its 325 Vassar Street facility, approximately 19,404 square feet, to LARONDE, Inc. ("LARONDE", formerly known as VL50, Inc.), which is an affiliate of Flagship. The sublease term will expire at the end of the Company's lease agreement with the landlord in September 2024. The rental rate for the sublease arrangement is equal to the Company's rental obligation per the agreement with BMR-325 Vassar Street LLC, reduced by the sublease income received from Cygnal Therapeutics, Inc. ("Cygnal"), approximating $1.3 million per year. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management. Under the sublease agreement, the Company received rental income of $0.6 million, which was recorded as a reduction of rental expenses, during the year ended December 31, 2020. As of December 31, 2020, there was no outstanding receivable due from LARONDE.

In September 2019, the Company sublet approximately 1,445 square feet of its 325 Vassar Street facility to Cygnal, which is an affiliate of Flagship, for two years. The rental rate for the sublease arrangement is equal to the Company's rental obligation per the agreement with BMR-325 Vassar Street LLC, approximating $0.1 million per year. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management. Under the sublease agreement, the Company received rental income of $0.1 million and $36 thousand, which was recorded as reduction of rental expenses, during the years ended December 31, 2020 and 2019, respectively. There was no outstanding receivable due from Cygnal as of December 31, 2020, and an immaterial amount of outstanding receivable was due from Cygnal as of December 31, 2019.

16. Employee benefits

In 2018, the Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum

age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company is not required to make and has not made any matching contributions to the 401(k) Plan to date.

17. Subsequent events

The Company evaluated all subsequent events through May 7, 2021, the date that these financial statements were issued to determine if such events should be reflected in these financial statements.

Non-exclusive license agreement with Acuitas

As discussed in Note 9, *License agreements*, the Acuitas' Development and Option Agreement grants the Company options to obtain a license under the Acuitas LNP Technology. 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's lipid nanoparticles. In connection with the option exercise, the Company paid Acuitas an 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 particular 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.

Issuance and sale of Series C Preferred Stock

In March 2021, the Company issued and sold 41,833,328 shares of Series C Preferred Stock, at a price of $3.00 per share, for gross proceeds of $125.5 million. The terms of the Series C Preferred Stock are substantially the same as the terms of the Series A and Series B Preferred Stock. In connection with the issuance, the Company increased the number of authorized shares of preferred stock from 107,125,232 shares to 132,858,564 shares.

Extension of debt repayment date and maturity date

As a result of the closing of Series C Preferred Stock, the Company has satisfied the cash proceeds milestone as defined in the Third Amendment, in which the Company has received gross cash proceeds of more than $50.0 million from the issuance of new preferred stock prior to June 30, 2021. Accordingly, the principal repayment date of the term loan will be extended to December 31, 2021 and the maturity date will be extended to December 31, 2023. There are no other changes to the terms as a result of the achievement of the cash proceeds milestone.

Shares

Common Stock

Prospectus

Goldman Sachs & Co. LLC **Jefferies** **Piper Sandler**

Wedbush PacGrow

, 2021

Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

	Amount
Securities and Exchange Commission registration fee	$ *
FINRA filing fee	*
Initial listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Transfer Agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our restated certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our restated certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended , or the Securities Act, against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuance of Capital Stock.

From August 2017 to June 2019, the registrant issued an aggregate of 51,000,000 shares of Series A preferred stock for aggregate consideration of $25.5 million and 5,775,232 shares of Series A Preferred Stock in converted promissory notes upon the cancellation of principal debt totaling $2,833,534 principal plus $54,081 accrued interest to accredited investors pursuant to Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

From January 2020 to August 2020, the registrant issued an aggregate of 32,399,999 shares of Series B preferred stock for aggregate consideration of approximately $48.6 million to accredited investors pursuant to Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

In March 2021, the registrant issued an aggregate of 41,833,328 shares of Series C preferred stock for aggregate consideration of approximately $125.5 million to accredited investors pursuant to Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

(b) Equity Grants.

From June 3, 2018 through May 3, 2021 the registrant granted stock options to purchase an aggregate of 22,306,485 shares of its common stock with exercise prices ranging between $0.11 and $1.50 per share to employees, non-employees, and directors in connection with services provided to the registrant by such parties, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act or pursuant to Section 4(a)(2) of the Securities Act as transactions not involving a public offering.

(c) Warrants.

On September 30, 2019, the registrant issued an amended and restated warrant to purchase up to an aggregate of 350,000 shares of Series A preferred stock to PacWest Bancorp pursuant to Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description of Exhibit
1.1*	Underwriting Agreement
3.1*	Amended and Restated Certificate of Incorporation of the Registrant, as amended (currently in effect)
3.2*	Bylaws of the Registrant (currently in effect)
3.3*	Form of Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4*	Form of Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
4.1*	Amended and Restated Investors' Rights Agreement, dated March 4, 2021
4.2*	Specimen Stock Certificate evidencing the shares of common stock

Exhibit Number	Description of Exhibit
4.3*	Amended and Restated Warrant to Purchase Stock issued to PacWest Bancorp, dated September 30, 2019, to purchase Series A preferred stock
5.1*	Opinion of Latham & Watkins LLP
10.1*	2017 Equity Incentive Plan, as amended, and form of option agreements thereunder
10.2*	2021 Incentive Award Plan and form of option agreements thereunder
10.3*	2021 Employee Stock Purchase Plan
10.4*	Non-Employee Director Compensation Program
10.5*	Offer Letter between Mahesh Karande and the Registrant, dated March 2, 2019
10.6*	Offer Letter between Tom McCauley and the Registrant, dated July 10, 2019
10.7*	Offer Letter between Roger Sawhney and the Registrant, dated March 25, 2020
10.8*	Form of Indemnification Agreement for Directors and Officers
10.9*	Shared Space Arrangement between Kintai Therapeutics, Inc. and the Registrant, dated July 13, 2020
10.10*	Lease Agreement between BMR-325 Vassar Street LLC and the Registrant, dated November 30, 2017
10.11*	Loan and Security Agreement between Pacific Western Bank and the Registrant, dated March 9, 2018, as amended on September 30, 2019, January 22, 2020 and December 30, 2020.
10.12†*	License Agreement between Flagship Pioneering Innovations V, Inc. and the Registrant, dated March 12, 2019
10.13†*	Exclusive License Agreement between the Whitehead Institute for Biomedical Research and the Registrant, dated May 22, 2019
10.14†*	Co-Exclusive License Agreement between the Whitehead Institute for Biomedical Research and the Registrant, dated May 22, 2019
23.1*	Consent of Deloitte & Touche LLP
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

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

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on this day of , 2021.

Omega Therapeutics, Inc.

By: _____
Mahesh Karande
President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Omega Therapeutics, Inc., hereby severally constitute and appoint Mahesh Karande and Roger Sawhney, M.D., and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
Mahesh Karande	President, Chief Executive Officer and Director (principal executive officer)	, 2021
Roger Sawhney, M.D.	Chief Financial Officer (principal financial officer and principal accounting officer)	, 2021
Noubar B. Afeyan, Ph.D.	Chairman of the Board of Directors	, 2021
David A. Berry, M.D., Ph.D.	Director	, 2021
Elliott M. Levy, M.D.	Director	, 2021
John Mendlein, Ph.D., J.D.	Director	, 2021
Mary T. Szela	Director	, 2021
Richard A. Young, Ph.D.	Director	, 2021