

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD  
FROM TO**

Commission File Number 001-39376

**POSEIDA THERAPEUTICS, INC.**

(Exact name of Registrant as specified in its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
9390 Towne Centre Drive  
San Diego, CA  
(Address of principal executive offices)

47-2846548  
(I.R.S. Employer  
Identification No.)

92121  
(Zip Code)

Registrant's telephone number, including area code: (858) 779-3100

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.0001 par value per share	PSTX	Nasdaq Global Select Market

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES  NO

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant as of June 30, 2021 was approximately \$357.1 million, based on the closing price of the Registrant's common stock as reported by The Nasdaq Global Select Market on such date.

The number of shares of the Registrant's common stock outstanding as of March 4, 2022 was 62,546,899.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive Proxy Statement for the 2022 Annual Meeting of Stockholders, which proxy statement will be filed not later than 120 days after the end of the fiscal year covered by this report.

Auditor Firm Id: 238

Auditor Name: PricewaterhouseCoopers LLP

Auditor Location: San Diego, California

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## Special Note Regarding Forward-Looking Statements

This Annual Report includes forward-looking statements. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements, including statements about:

- our expectations regarding the timing, scope and results of our development activities, including our ongoing and planned clinical trials;
- the timing of and plans for regulatory filings;
- our plans to obtain and maintain regulatory approvals of our product candidates in any of the indications for which we plan to develop them, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the potential benefits of our product candidates and technologies;
- our expectations regarding the use of our platform technologies to generate novel product candidates;
- the market opportunities for our product candidates and our ability to maximize those opportunities;
- our business strategies and goals;
- estimates of our expenses, capital requirements, any future revenue, and need for additional financing;
- our expectations regarding manufacturing capabilities and plans;
- the performance of our third-party suppliers and manufacturers;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our platform technologies and product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding developments and projections relating to our competitors, competing therapies that are or become available, and our industry;
- our expectations regarding the impact of the COVID-19 pandemic on our business, our industry and the economy;
- future changes in or impact of law and regulations in the United States and foreign countries; and
- the sufficiency of our existing cash, cash equivalents and short-term investments to fund our operations.

The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would” or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives and financial needs.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the SEC with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

## Summary of Risks Associated with Our Business

*Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found in the section titled "Risk Factors" and should be carefully considered.*

- The COVID-19 pandemic continues to adversely impact our business, including our clinical trials, supply chain and business development activities.
- We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated any revenue from product sales and may never be profitable.
- We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- Our product candidates are in the early stages of development and we have a limited history of conducting clinical trials to test our product candidates in humans.
- Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.
- Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our gene engineering technologies and resulting product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.
- If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

## PART I

### Item 1. Business.

We are a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary gene engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac DNA Delivery System, Cas-CLOVER site-specific gene editing system and nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics.

Within cell therapy, we believe our technologies allow us to create product candidates with engineered cells that engraft in the patient's body and drive lasting durable responses that may have the capacity to result in single treatment cures. Our chimeric antigen receptor T cell, or CAR-T, therapy portfolio currently consists of both autologous and allogeneic, or off-the-shelf, product candidates. No allogeneic CAR-T cell products have successfully completed clinical development and been approved for marketing yet due in part to the need for a gene editing technology in their production, but this approach has the potential to be the next significant advance in the field as ready to use, off-the-shelf products of consistently high quality. We are advancing a broad pipeline with a plan to have up to five CAR-T product candidates in the clinic by 2023 in both hematological and solid tumor oncology indications. Our most advanced product candidate, P-PSMA-101, is an autologous CAR-T being developed for the treatment of patients with metastatic castrate resistant prostate cancer, or mCRPC, currently in a Phase 1 trial. We have also initiated clinical trials for our first two fully allogeneic CAR-T product candidates, P-BCMA-ALLO1 and P-MUC1C-ALLO1. P-BCMA-ALLO1 is currently in a Phase 1 trial, being developed for patients with relapsed/refractory multiple myeloma, using the learnings from our first autologous program P-BCMA-101. P-MUC1C-ALLO1 is also currently in a Phase 1 trial and has the potential to treat a wide range of solid tumors, including breast, ovarian and other epithelial-derived cancers. In addition, we have several additional allogeneic programs advancing toward anticipated IND filings, including P-CD19CD20-ALLO1 for which we expect an IND filing in the first half of 2023.

Within gene therapy, we believe our technologies have the potential to create next generation therapies that can deliver long-term, stable gene expression that does not diminish over time and may have the capacity to result in single treatment cures. Our first liver-directed gene therapy product candidate is for the orphan genetic disease ornithine transcarbamylase, or OTC, deficiency. In addition, we have a collaboration with Takeda Pharmaceutical Company Limited, or Takeda, to develop up to six liver and hemopoietic stem cell (HSC) programs, including the P-FVIII-101 program using a fully nanoparticle approach for treating Hemophilia A. We believe our proprietary gene engineering technologies have the potential to address the limitations of the transient nature of traditional gene therapies, thereby offering distinct advantages in liver-directed gene therapy. Furthermore, we believe that we have the potential to pursue multiple *in vivo* and *ex vivo* approaches in a wide array of cell types and tissues for non-liver-directed gene therapies.

Across our pipeline, we seek to leverage the unique aspects and capabilities of our core platform technologies to create cell and gene therapeutic product candidates that: (1) are differentiated by potent and durable activity and tolerability, (2) may allow us to address indications that are not accessible with the current generation of cell and gene therapeutics, and (3) may allow for widespread patient accessibility enabling broader commercial adoption.

#### ***Differentiation based on potent and durable activity and tolerability:***

***Cell Therapy.*** Our non-viral piggyBac DNA Delivery System allows us to design CAR-T product candidates that can not only deliver very large CAR-containing transgenes to T cells, but also generate CAR-T products that deliver a high percentage of early memory T cells, such as stem cell memory T, or T<sub>SCM</sub>, cells. T<sub>SCM</sub> cells are a stem cell form of T cells that engraft, self-renew and mature into every T cell subtype, including the effector T, or T<sub>EFF</sub>, cells, which are tumor killing cells. We believe delivering a high percentage of T<sub>SCM</sub> cells will drive more gradual tumor killing, thereby inducing less inflammatory cytokine response and improving the tolerability profile of our CAR-T product candidates relative to those of existing CAR-T therapies. We believe that, through these T<sub>SCM</sub> cells, we can deliver a predominantly self-renewing CAR-T “prodrug” that can engraft and produce unlimited T<sub>EFF</sub> “drug”, an approach that potentially results in more potent activity and duration of response.

***Gene Therapy.*** PiggyBac confers many potential advantages compared to current gene therapies that rely on traditional viral-based delivery methods. In preclinical studies, piggyBac transgene delivery exhibited high-level, long-term, stable gene expression and allowed for permanent gene integration into DNA. In contrast, traditional viral vectors used for *in vivo* gene therapy, such as adeno-associated virus, or AAV alone, which is a virus that can be engineered to deliver DNA to target cells, when used alone are unable to permanently integrate into DNA and thus result in transient therapeutic transgene expression, which decreases over time. PiggyBac's ability to deliver high levels of stable integration and therapeutic transgene expression may also enable lower dosing when used in combination with AAV. Furthermore, in our preclinical studies the controlled integration of piggyBac has been shown to be

non-mutagenic and non-oncogenic, which we believe makes it better suited as a delivery vehicle than AAV alone. As compared to nanoparticle alone-based delivery approaches, which similar to AAV alone approaches are transient in nature, nanoparticle combined with piggyBac may result in integration and stable therapeutic transgene expression and may also avoid the immunogenicity issues that are often associated with viral-based delivery methods.

#### **Ability to address indications currently inaccessible by cell and gene therapeutics:**

*Cell Therapy.* We believe the ability of our CAR-T product candidates to engraft and produce a potentially unlimited number of T<sub>EFF</sub> cells is a critical advantage that has allowed our use of CAR-T to move beyond hematological tumors and into solid tumors, an area historically limited due to the lack of persistence and durability of therapeutic cells needed to produce a clinical impact.

*Gene Therapy.* We are utilizing advantages that we have engineered in our piggyBac, nanoparticle and AAV-based gene delivery technologies to potentially overcome many of the limitations of current *in vivo* gene therapies. PiggyBac's ability to permanently integrate into DNA enables us to extend our reach into diseases associated with many tissues of the body that contain either dividing or non-dividing cells, a feature not available to transient viral-based delivery methods. Additionally, our potential to enable durable gene expression within tissues with rapidly dividing cells should enable us to pursue the entire spectrum of genetic diseases including many indications within the pediatric population.

#### **Widespread patient accessibility enabling broader commercial adoption:**

*Cell Therapy.* CAR-T treatments have faced both cost and safety challenges. Our engineering of proprietary booster molecules allows us to potentially generate hundreds of doses from a single manufacturing run in our fully allogeneic CAR-T program. We believe this will lead to a significant reduction in costs to levels in the range of traditional biologic therapeutics in oncology. Additionally, piggyBac is intrinsically more cost effective than historical CAR-T methods as it utilizes nucleic acids, DNA and RNA produced using good manufacturing practices, or GMP, which are faster and cheaper to produce than GMP virus. Our focus on T<sub>SCM</sub>, first initiated in our autologous CAR-T product candidates, offers potential tolerability benefits and has demonstrated the potential of our approach to limit cytokine release syndrome, or CRS, and neurotoxicity that has limited the broad commercial adoption and utility of existing autologous CAR-T therapeutics. As a result of its tolerability profile and following discussions with the FDA, in P-BCMA-101, our first Phase 1 clinical trial in CAR-T, we were able to dose 24 patients on a fully outpatient basis, which we believe could translate to our other programs and support broader commercial adoption, if approved.

*Gene Therapy.* PiggyBac's ability to permanently integrate into the DNA yields the potential to provide more durable responses within gene therapy for many diseases that current viral-based approaches are unable to address. Importantly, we believe piggyBac will drive our potential ability to deliver single treatment cures, overcoming the limitations of viral-based therapies related to tolerability and durability. PiggyBac in combination with AAV may enable lower dosing, thereby improving tolerability and reducing costs. In other product candidates, nanoparticle delivery of piggyBac will eliminate the need for AAV and may further improve tolerability and reduce cost. We believe these characteristics will potentially yield significant commercial advantages and confer meaningful pharmacoeconomic benefits to payors potentially resulting in broader commercial adoption, if approved.

#### **Our Proprietary Cell and Gene Engineering Platform Technologies**

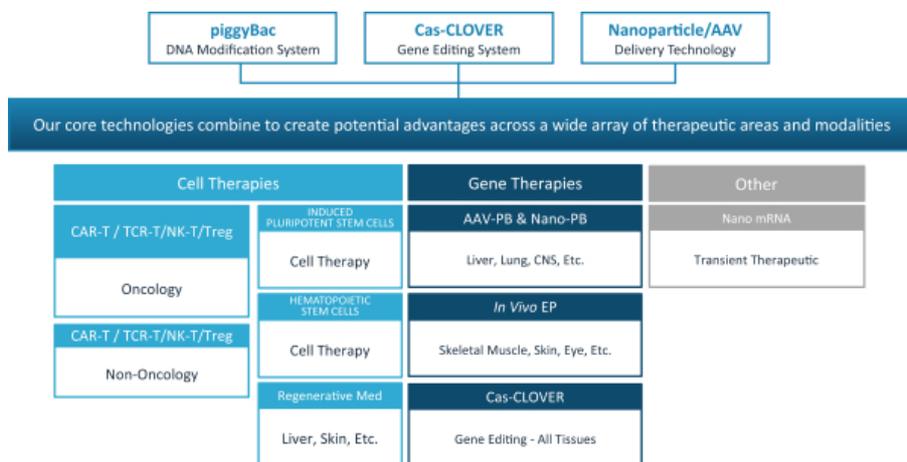
We have developed a proprietary suite of gene engineering technologies that have broad utility. The breadth and depth of our technology platforms fall into three primary categories: (1) non-viral gene insertion, (2) gene editing and (3) gene delivery, supported by CAR-T tools.

- **Non-viral gene insertion.** Our proprietary, non-viral piggyBac DNA Delivery System, which includes our Super piggyBac transposase enzyme, is highly efficient at stable gene insertion and has a significantly larger genetic cargo capacity as compared to viral methods (potentially greater than 20x lentivirus). As a result, our product candidates can contain transgenes large enough to include multiple chimeric antigen receptor, or CAR, and/or T cell receptor, or TCR, genes, selection genes, safety switch genes and potentially other cargo for specific treatment applications, making it a highly versatile platform. Importantly, piggyBac works in a wide variety of cell types, both dividing and non-dividing, T cells, B cells, natural killer cells, hematopoietic stem cells, or HSCs, induced pluripotent stem cells, primary hepatocytes and numerous other cell types giving it broad reach and applicability.
- **Gene editing with precise specificity.** Our proprietary, highly precise Cas-CLOVER site-specific gene editing technology is easy to use, highly efficient and capable of multiplexing and has shown low to no off-target activity in our preclinical studies, which we believe provides a distinct tolerability advantage over other gene editing systems. In addition, unlike many other gene editing technologies, Cas-CLOVER can efficiently edit resting T cells, allowing for the maintenance of the highly desirable T<sub>SCM</sub> product composition in allogeneic product candidates, an important component of our CAR-T

approach. Both of our proprietary site-specific gene editing platforms, Cas-CLOVER, and a related technology called TAL-CLOVER, can also be used for *in vivo* gene therapies.

- **Gene delivery.** We have numerous technologies and platforms for delivering DNA, RNA and proteins, including into cells both *ex vivo* and *in vivo*. These include nanoparticle technology, AAV technology, and both *ex vivo* and *in vivo* electroporation, which is a process by which we use a pulse of electricity to briefly increase the permeability of cells.
- **Additional proprietary tools.** We also have a number of other technologies and tools that have been developed for specific applications including:
  - ***T<sub>SCM</sub> Phenotype.*** We have developed and patented a number of manufacturing methods and media to preserve a high percentage of T<sub>SCM</sub> in our product candidates. We believe that the T<sub>SCM</sub> cell phenotype is key to success in CAR-T therapies.
  - ***Positive selection.*** We create product candidates utilizing a fully human drug resistance gene that can be employed during manufacturing to create a purified product that is essentially 100% CAR-positive, minimizing one of the sources of CAR-T toxicity and thereby potentially enhancing the therapeutic index. Our initial use for positive selection is for CAR-T, but this technology has utility in other cell types.
  - ***Booster molecules.*** We have developed a technology that enables improved expansion of gene-edited allogeneic cells without affecting their desirable T<sub>SCM</sub> characteristics. The booster molecule is an RNA-based technology introduced to T cells during the manufacturing process, which results in transient expression of a receptor on the surface of T cells that allows the cells to respond to antibody-based activator molecules, resulting in significant expansion of the cells without causing maturation or exhaustion of the cells. Using this approach, we can create potentially hundreds of doses from a single manufacturing run yet maintain the high percentage of desirable T<sub>SCM</sub> cells in the final product candidate. This technology is currently used in our allogeneic CAR-T programs but may have utility in other cell types.
  - ***Safety switch.*** We have developed a proprietary safety switch comprised of fully human genes that can be activated by administration of a small molecule, and thereafter, has the potential to rapidly eliminate some or all of the genetically modified cells in the patient after administration.
  - ***CAR binding libraries.*** In addition to traditional scFv binders, we have access to and utilize novel binder technologies, such as heavy-chain-only antibody fragments, which, compared to scFv, are more stable, result in less T cell exhaustion and may result in lower immunogenicity.
  - ***Armoring platforms.*** We can use our genetic engineering tools to make other modifications to our product candidates to potentially improve their performance against solid tumors, an approach commonly referred to as “armoring”. We have several types of armoring platforms:
    - ***Conditional gene expression system:*** Due to the very large cargo capacity of piggyBac, we have demonstrated the ability to deliver into the genome a conditional gene expression system that expresses one or more genes of interest only when the cell becomes activated or stimulated by binding of the CAR molecule to its specific target. This approach is superior to constitutive expression systems in that tight conditional regulation limits gene expression to relevant sites, such as the tumor microenvironment. In this way, supporting molecules such as pro/anti-inflammatory molecules, checkpoint inhibitors, cytokines, interleukins and chemokines can be expressed by the T cell and/or delivered locally to the tumor or target cell.
    - ***Decoy receptors:*** CAR-T therapies can be enhanced by using piggyBac to deliver molecules that sequester and block negative immune regulators, such as PD-1 and TGFβR2. Decoy/null or positive switch receptors can be used to block or convert to activators, respectively, regulatory signals from the tumor microenvironment that otherwise work to exhaust T cell responses.
    - ***Gene knockout:*** Our Cas-CLOVER site-specific gene editing platform can be used to armor both autologous and allogeneic CAR-T therapies by targeting functional regulatory molecules, such as checkpoint blockade genes. These protein receptors are involved in exhaustion mechanisms by the tumor microenvironment.

These broad platform technologies, when used in various combinations, enable us to pursue a wide array of therapeutic modalities and indications. We believe this component of our strategy and business model will be a core value driver for us over the long term. The following graphic presents the broad utility of our platform technologies:



## Our Pipeline

Our broad and versatile set of proprietary platform technologies has allowed us to develop a deep pipeline of novel product candidates with composition of matter patent protection through at least 2037. Our initial focus is on CAR-T for oncology and liver-directed gene therapy programs for rare diseases.

### CAR-T for Oncology

The following table summarizes our current wholly-owned CAR-T for Oncology product candidate portfolio:

Indication	Candidate	Discovery	Preclinical	IND-Enabling	Phase 1	Phase 2
<b>CAR-T FOR ONCOLOGY</b>						
MULTIPLE MYELOMA	P-BCMA-ALLO1	Allo				
	P-BCMACD19-ALLO1	Allo				
PROSTATE CANCER	P-PSMA-101	Auto				
	P-PSMA-ALLO1	Allo				
SOLID TUMOR	P-MUC1C-ALLO1	Allo				
	Dual CAR (Undisclosed)	Allo				
B - CELL	P-CD19CD20-ALLO1	Allo				

### Autologous Program

Our autologous CAR-T product candidate is developed using a patient's own cells to treat their disease. We believe our ability to develop product candidates with a high percentage of T<sub>SCM</sub> cells may result in improved tolerability and the potential to see more durable responses than the current generation of CAR-T therapeutics. We are also exploring novel dosing strategies in our autologous program to more fully optimize clinical approaches. Importantly, all the learnings from our autologous programs have and continue to be transferred and utilized to inform and improve our allogeneic programs.

#### ***P-PSMA-101***

- Autologous CAR-T product candidate targeting prostate-specific membrane antigen, or PSMA, being developed to treat patients with mCRPC.
- We initiated a Phase 1 clinical trial and dosed the first patient in May 2020. Following a patient death, the trial was placed on clinical hold in August 2020 which was subsequently lifted in November 2020. The Phase 1 trial resumed in early 2021.
- We recently reported interim results from our Phase 1 clinical trial at the American Society of Clinical Oncology Genitourinary Cancers Symposium, or ASCO-GU, in February 2022. As of the data cutoff date of December 31, 2021, 14 patients had evaluable data. Ten of 14 (71%) patients demonstrated measurable declines in Prostate Specific Antigen, or PSA, levels, 5 of 14 (36%) patients showed a decline in PSA levels of 50% or more, and one patient who demonstrated evidence of complete tumor elimination and remains in a durable response of greater than ten months at the time of the ASCO-GU presentation.
- We recently amended the clinical protocol to include patients with salivary gland cancer, given the high unmet medical need.
- Manufactured using our non-viral piggyBac DNA Delivery System.
- We are also developing P-PSMA-ALLO1, an allogeneic version of this program.

#### ***Allogeneic Programs***

Our fully allogeneic CAR-T product candidates are developed using well-characterized cells derived from a healthy donor as starting material with the goal of enabling treatment of potentially hundreds of patients from a single manufacturing run. Doses are cryopreserved and stored at treatment centers for future off-the-shelf use.

#### ***P-BCMA-ALLO1***

- Allogeneic CAR-T product candidate targeting BCMA, being developed to treat relapsed/refractory multiple myeloma patients.
- We have designed P-BCMA-ALLO1 to be fully allogeneic, with genetic edits to eliminate or reduce both host-vs-graft and graft-vs-host alloreactivity.
- We received clearance from the FDA on our IND filing in the second half of 2021 and initial data from our Phase 1 clinical trial is expected in the second half of 2022.
- Manufactured using our proprietary Cas-CLOVER site-specific gene editing technology to reduce or eliminate reactivity, in addition to our piggyBac DNA Delivery System for non-viral gene insertion and our booster molecule technology for manufacturing scalability.
- Learnings from our first clinical trial, P-BCMA-101, an autologous program, were used to design our first allogeneic program, including the inclusion of a single chain VH BCMA binder and implementation of modifications we made to our manufacturing process using a nanoplasmid which translated into an increase in the depth and rate of responses at comparable doses in our P-BCMA-101 trial.
- Based on the findings from the P-BCMA-101 trial, we are including an arm in the trial for P-BCMA-ALLO1 to explore rituximab as part of our dosing strategy.

#### ***P-MUC1C-ALLO1***

- Allogeneic CAR-T product candidate for multiple solid tumor indications. We believe P-MUC1C-ALLO1 has the potential to treat a wide range of solid tumors derived from epithelial cells, such as breast, colorectal, lung, ovarian, pancreatic and renal cancers, as well as other cancers expressing a cancer-specific form of the Mucin 1 protein, or MUC1-C.
- P-MUC1C-ALLO1, our first allogeneic solid tumor program, was designed to leverage the learnings of our P-BCMA-ALLO1 and P-PSMA-101 programs. We have designed P-MUC1C-ALLO1 to be fully allogeneic, with genetic edits to eliminate or reduce both host-vs-graft and graft-vs-host alloreactivity.

- We have demonstrated the elimination of tumor cells to undetectable levels in a preclinical model of ovarian cancer and two models of breast cancer, including a model of triple negative breast cancer in which immuno-deficient mice were implanted with a human metastatic breast cancer cell line.
- We received clearance from the FDA on our IND filing in late 2021 and expect initial clinical data from our Phase 1 clinical trial in the second half of 2022.
- Manufactured using our proprietary Cas-CLOVER site-specific gene editing technology to reduce or eliminate reactivity, in addition to our piggyBac DNA Delivery System for non-viral gene insertion and our booster molecule technology for manufacturing scalability.

**P-CD19CD20-ALLO1**

- Our first dual CAR allogeneic CAR-T product candidate targeting CD19 and CD20 being developed to treat patients with B-Cell malignancies. Dual CAR product candidates contain two fully functional CAR molecules to target cells that express at least one of the two intended targets.
- We have designed P-CD19CD20-ALLO1 to be fully allogeneic, with genetic edits to eliminate or reduce both host-vs-graft and graft-vs-host alloreactivity.
- We anticipate an IND filing and initiation of a Phase 1 clinical trial in the first half of 2023.
- Manufactured using our proprietary Cas-CLOVER site-specific gene editing technology to reduce or eliminate reactivity, in addition to our piggyBac DNA Delivery System for non-viral gene insertion and our booster molecule technology for manufacturing scalability.

*Additional Allogeneic Programs*

We have strategically designed our initial and upcoming clinical programs in order to best utilize the findings from our early studies to inform further pipeline development. We have several preclinical programs intended to represent second or third generation programs for our various targets, and are exploring additional indications utilizing different capabilities of our platform, such as dual CAR approaches.

**Gene Therapy**

The following table summarizes our current gene therapy product candidate portfolio including a representation of programs that we partnered with Takeda in 2021:

Indication	Candidate	Discovery	Preclinical	IND-Enabling	
<b>GENE THERAPIES</b>					
ORNITHINE TRANSCARBAMYLASE DEFICIENCY (OTC)	P-OTC-101				
HEMOPHILIA A	P-FVIII-101				
LIVER-DIRECTED #2	UNDISCLOSED				
LIVER-DIRECTED #3	UNDISCLOSED				
LIVER-DIRECTED #4	UNDISCLOSED				
HSC-DIRECTED #1	UNDISCLOSED				
HSC-DIRECTED #2	UNDISCLOSED				

Our gene therapy product candidates have been developed by utilizing our piggyBac technology together with AAV or our nanoparticle technology to overcome the major limitations of traditional AAV gene therapy. We believe that our approach will result in integration and long-term stable expression at potentially much lower doses than AAV technology alone, thus also conferring cost and tolerability benefits. Our eventual goal is to completely replace AAV with our nanoparticle technology, freeing future product development in gene therapy of AAV limitations.

**P-OTC-101.** P-OTC-101 is a liver-directed gene therapy combining piggyBac technology with AAV and nanoparticles for the *in vivo* treatment of OTC deficiency. OTC deficiency is an often fatal or morbid urea cycle disease caused by congenital mutations

in the OTC gene with a high unmet medical need. We are currently evaluating whether to modify the P-OTC-101 program to move completely to our non-viral nanoparticle delivery system.

**P-FVIII-101.** P-FVIII-101 is a liver-directed gene therapy combining piggyBac technology with our nanoparticle delivery technology for the *in vivo* treatment of Hemophilia A. Hemophilia A is a bleeding disorder caused by a deficiency in Factor VIII production with a high unmet need. Our preclinical data demonstrates an ability to correct this deficiency to near normal levels in a juvenile mouse model using nanoparticle delivery of our P-FVIII-101 potential product candidate. As of October 2021, our P-FVIII-101 program is included in the collaboration and license agreement with Takeda, or the Takeda Collaboration Agreement, and Takeda will be responsible for all future development costs and timeline disclosures.

**Additional Takeda funded Programs.** In October 2021, we entered into the Takeda Collaboration Agreement, pursuant to which we granted to Takeda a worldwide exclusive license under our piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms to research, develop, manufacture and commercialize gene therapy products for certain indications, including Hemophilia A. In addition to P-FVIII-101, as part of the Takeda Collaboration Agreement, we granted Takeda a license to five additional undisclosed preclinical programs in both liver and HSC-directed indications. We are obligated to lead research activities up to candidate selection, after which Takeda is obligated to assume responsibility for further development, manufacturing and commercialization of each program. Takeda will be responsible for all future development costs and timeline disclosures for these programs as well. Takeda is also obligated to provide funding for all collaboration program development costs. Takeda also has an option to elect up to two additional programs for a total of eight programs should that option be exercised.

## Our Strategy

Our mission is to develop next generation cell and gene therapeutics with the capacity to cure.

We intend to develop and commercialize novel cell and gene therapy products by using our broad gene engineering platform technologies to treat patients with high unmet medical need across a wide of array of indications. Our current pipeline includes autologous and allogeneic CAR-T product candidates for oncology indications and piggyBac + AAV and piggyBac + nanoparticle product candidates as liver-directed gene therapy programs for orphan genetic diseases. We plan to pursue our mission through the following strategies:

**Rapidly develop and commercialize allogeneic CAR-T therapies targeting hematological malignancies.** We are developing P-BCMA-ALLO1, a product candidate for patients with relapsed/refractory multiple myeloma, to address cost and safety limitations of current CAR-T therapies utilized in this indication. Over time, we plan to develop our product candidates in earlier lines of treatment and for other hematological malignancies and will seek to commercialize in community hospital settings, and eventually in outpatient infusion sites. Our approach for P-BCMA-ALLO1 is using the findings from our P-BCMA-101 autologous program, which based on the toxicity profile observed in the Phase 1 clinical trial and following discussions with the FDA allowed us to dose on a fully outpatient basis.

**Leverage the strength and breadth of our platform technologies to develop autologous and allogeneic CAR-T therapies in solid tumors.** Our platform technology is designed to address the historical CAR-T limitations in treating solid tumors, which result from the lack of product persistence needed to have a clinical impact on these indications. We are advancing both P-PSMA-101 and P-MUC1C-ALLO1 as candidates for the treatment of solid tumors. P-PSMA-101 is an autologous CAR-T candidate being evaluated in a Phase 1 clinical trial in which patient dosing was initiated in May 2020 and enrollment resumed in late 2020 after a clinical hold from August to November 2020 following a patient death. As we continue evaluating the findings from P-PSMA-101, including safety and efficacy in the clinic, we may decide to accelerate our allogeneic version of this product candidate, P-PSMA-ALLO1. In addition, due to the promising preclinical data we are seeing from P-BCMA-ALLO1 and initial efficacy in our first solid tumor program, P-PSMA-101, we decided to advance our first CAR-T targeting MUC1-C, P-MUC1C-ALLO1, as a fully allogeneic program. P-MUC1C-ALLO1 received IND clearance by the FDA in late 2021 and we initiated a Phase 1 clinical trial and expect initial clinical data in the second half of 2022.

**Utilize our platform technologies to pursue liver-directed gene therapy programs.** Our lead gene therapy product candidates, P-OTC-101 and P-FVIII-101, utilize our piggyBac technology combined with AAV or nanoparticles to target orphan genetic diseases with the goal of developing single-treatment cures. Over time, we intend to develop additional therapies for rare diseases and to replace AAV technology with nanoparticle-based delivery of our *in vivo* gene therapies. We believe that nanoparticle delivery of gene therapy could be a major advancement over AAV delivery by improving tolerability, lowering cost, allowing for re-dosing and addressing indications that AAV will not be able to effectively address, including diseases where correction necessitates delivery of large therapeutic transgenes. We and our current and future collaborators, including Takeda, currently plan to develop, and if approved, commercialize our gene therapy product candidates.

**Utilize our technology and capabilities to develop allogeneic multi-CAR-T products.** Our Dual-CAR allogeneic product candidates include P-CD19CD20-ALLO1 for B cell malignancies and potentially some autoimmune diseases, P-BCMACD19-ALLO1 for multiple myeloma and an undisclosed Dual CAR for solid tumors. We believe these multi-CAR programs highlight the ability of our piggyBac platform to enable product candidates that other technologies will not be able to achieve easily, if at all. We plan to continue developing multi-CAR product candidates, which we believe could represent a next generation of CAR-T therapies.

**Evaluate strategic partnerships and structures to create value and continue to innovate and develop our platform technologies.** Our platform technologies are highly differentiated with the ability to create many product candidates across a wide array of therapeutic modalities and indications. As such, we intend to seek partnerships and collaborations to expand our reach and create additional value in pursuit of our mission. In addition, we may evolve our corporate structure to implement a holding company or similar structure in order to maximize the value of our platform technologies and product candidates. In October 2021, we signed the Takeda Collaboration Agreement to further expand our gene therapy efforts. Given the breadth of our technology, we believe there are additional areas in which we could evaluate strategic partnerships.

## Our Team

We are led by an experienced management team with an unwavering commitment to developing next generation cell and gene therapeutics with the capacity to cure. Our Chief Executive Officer, Mark J. Gergen, J.D., has over 25 years of experience in healthcare and life science companies and most recently served as our President and Chief Business Officer, until his recent transition to CEO in February 2022. Prior to joining our company in early 2018, Mr. Gergen was part of the executive management team for a number of successful biotechnology companies, including Amylin Pharmaceuticals, Mirati Therapeutics, and Halozyme Therapeutics. Our Executive Chairman, Eric Ostertag, M.D., Ph.D., was the first graduate from the Gene Therapy Program at the University of Pennsylvania and has over 20 years of experience in cell and gene engineering, founding multiple biotechnology companies, including Transposagen Biopharmaceuticals. Dr. Ostertag served as Transposagen's Chief Executive Officer for 13 years, developing next-generation gene engineering technologies that were eventually spun out to create Poseida Therapeutics, in early 2015, and served as our CEO from our founding, until his recent transition to Executive Chairman in February 2022. As of December 31, 2021, the management team was supported by 263 employees, 135 of whom hold advanced degrees, including 64 with a Ph.D. and/or M.D. degree, and many with extensive experience in drug discovery and development.

## Our Proprietary Platform Technologies

We believe we are well-positioned to drive the continued advancement of CAR-T therapies for the treatment of oncology indications, as well as gene therapies for severe orphan genetic diseases with the mission to create next generation product candidates with the capacity to cure. We have developed our genetic engineering technologies to overcome the primary limitations of current generation cell and gene therapeutics. Our technologies are highly differentiated and designed to provide potentially significant advantages as highlighted below:

- PiggyBac DNA Delivery System – advantages in cell therapy applications
  - Preferentially delivers therapeutic transgenes to T<sub>SCM</sub> cells
  - Works in resting T cells, which is important in preserving T<sub>SCM</sub> cells
  - Very large cargo capacity allows insertion of additional molecules, including multi-CAR and/or TCR approaches
- PiggyBac DNA Delivery System – advantages for *in vivo* gene therapy applications
  - Permanent and stable therapeutic transgene integration into DNA
  - Works efficiently in dividing and non-dividing cells and tissues
  - Potential to address pediatric liver indications
  - May enable single-treatment cures
- Cas-CLOVER Site-Specific Gene Editing – advantages in cell therapy applications
  - Ability to perform highly efficient multiplexed gene editing enables fully allogeneic CAR-T product candidates
  - Efficient editing in resting T cells, which is important in preserving T<sub>SCM</sub> phenotype in CAR-T
  - Precise gene editing: high on-target site specificity with no to very low off target activity minimizes tolerability concerns
- Cas-CLOVER Site-Specific Gene Editing – advantages in gene therapy applications
  - Enables *in vivo* gene editing
  - Works in all types of cells and tissues tested to date

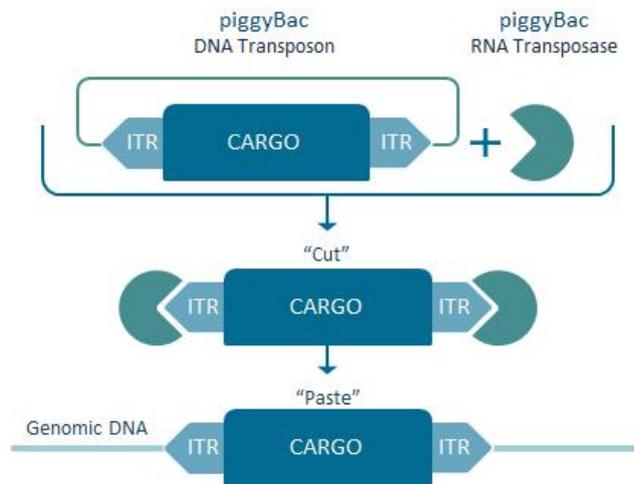
- Nanoparticle / AAV Delivery Technologies
  - Enable both *ex vivo* and *in vivo* gene therapies
  - Deliver piggyBac and Cas-CLOVER Systems to nearly any cell type or tissue
- Proprietary Tools, such as Booster Molecules
  - Booster molecules have the potential to overcome the “Allo Tax”, which commonly refers to the suboptimal manufacturing yield and characteristics of CAR-T products due to genetic modification, by enabling improved expansion of genetically modified T cells
  - Enable expansion of T cells without affecting their desirable T<sub>SCM</sub> characteristics
  - Allow us to create potentially hundreds of doses from a single healthy donor

Our technology platforms fall into three primary categories: (1) non-viral gene insertion, (2) gene editing and (3) gene delivery, supported by CAR-T tools; and have broad utility and serve as the foundation of our development programs.

**Non-viral gene insertion: piggyBac DNA Delivery System**

DNA transposons are genetic elements that efficiently move from a plasmid to a chromosome via a cut and paste mechanism. DNA transposons have been used as a gene transfer method, including in CAR-T manufacturing. The piggyBac DNA Delivery System is our proprietary non-viral gene engineering technology that can be used to add therapeutic transgene DNA to the genome using the highly efficient Super piggyBac transposase enzyme, a hyperactive enzyme that was genetically modified to enable very high efficiency transposition of piggyBac transposons. We believe piggyBac enables efficient and precise transposition and multiple differentiated product attributes.

The image below depicts the piggyBac DNA Delivery System:



Therapeutic genes encoded within the cargo region of the piggyBac DNA transposon transgene are flanked by non-translated inverted terminal repeat sequences, or ITRs, that are specifically recognized by the transposase enzyme for the highly efficient process of stably integrating the therapeutic transgene cargo into specific sequences (TTAA nucleotides) in the genome. The transposase enzyme can be co-delivered to the cell as a protein or encoded in either DNA or RNA.

The piggyBac platform is our core technology used for the development of CAR-T and other gene therapy product candidates in our pipeline. We believe our piggyBac DNA Delivery System enables multiple differentiated product attributes including:

- CAR-T product candidates with a high percentage of desirable T<sub>SCM</sub> cells, leading to better engraftment and duration of response with the potential for re-response, as well as a better tolerability profile;

- very large cargo capacity (potentially greater than 20x lentivirus)—allows efficient delivery of large therapeutic transgenes, including the possibility of multiple CAR or TCR molecules and incorporation of selection genes, safety switches and/or armoring strategies;
- non-viral delivery system that reduces the risk of mutagenesis and oncogenesis compared to viral delivery systems;
- high insertion efficiency and stable therapeutic transgene expression in a wide range of dividing and non-dividing cells and tissues; and
- shorter timelines and less costly manufacturing than viral methods.

As discussed previously, the piggyBac transposon preferentially transposes therapeutic transgenes into early memory T cells, including T<sub>SCM</sub> cells. We believe retroviral transgene delivery methods, such as lentivirus and  $\gamma$ -retrovirus, are not efficient at delivering transgenes into early memory T cells. This is a key differentiator that allows us to manufacture CAR-T products with a high percentage of T<sub>SCM</sub> cells, giving them desirable characteristics.

While the genetic cargo capacity of viruses typically used in CAR-T manufacturing, such as lentivirus and  $\gamma$ -retrovirus, is limited to approximately 10-20 kilobases, or kb, piggyBac has demonstrated cargo delivery of greater than 200 kb, allowing transfer of multiple useful genes. The very large cargo capacity of piggyBac permits incorporation of multiple genes into our product candidates to further enhance tolerability and potency, with all CAR-T cells in our current CAR-T product candidates carrying a CAR molecule gene, a safety switch gene and a selection gene. The cargo capacity also allows for packaging of multiple CAR-T encoding genes and/or TCR genes allowing for the creation of dual and other multi-CAR-T product candidates.

PiggyBac ITRs and other components act as strong insulators, ensuring stable transgene expression and reducing risks of oncogenesis. PiggyBac has shown lower integration into intragenic regions compared with lentivirus, meaning that it is less likely to cause a detrimental mutation.

Additionally, piggyBac is estimated to have a significantly lower cost in production of GMP material and a much shorter timeline for GMP production as compared to GMP production of viral vectors.

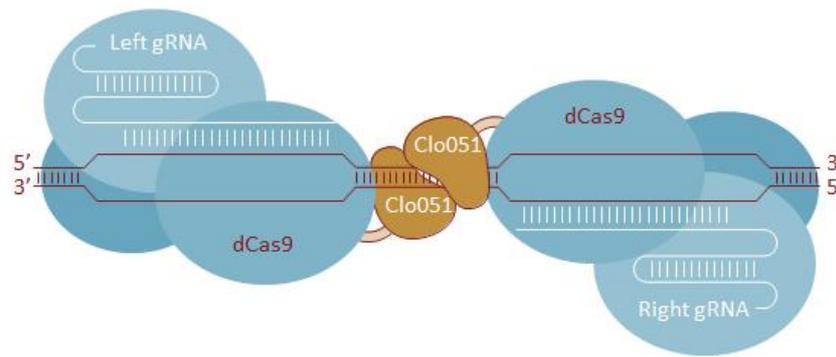
The image below depicts our piggyBac transposon transgene approach for creating CAR-T product candidates:



#### **Gene Editing with Precise Specificity: Cas-CLOVER Site-Specific Gene Editing Technology**

We have developed gene editing technology that uses a proprietary obligate homodimer nuclease system named CLOVER, which consists of parts of the Type IIS restriction endonuclease, Clo051. Genome cutting by this enzyme is strictly dependent upon dimerization, which makes it a fully dimeric system and gives it precise site-specificity. Cas-CLOVER uses a CRISPR (Clustered, Regularly Interspaced Short Palindromic Repeats) associated protein 9, or Cas9, enzyme that has been permanently altered and is unable to cut DNA (called dCas9). The dCas9 acts only as a DNA binding protein when combined with an appropriate guide RNA (gRNA). Cas-CLOVER combines the advantages of the first-generation CRISPR system (ease of design, low cost, multiplexing ability) with the advantages of the obligate homodimer nuclease systems (precise specificity). Importantly for T cell applications, Cas-CLOVER works well in resting T cells, which allows us to avoid maturation and exhaustion during production and assists in preserving the T<sub>SCM</sub> phenotype.

## Cas-CLOVER Gene Editing System



The most widely used platform for gene editing is CRISPR and an associated protein, Cas9. This gene editing technology is derived from a naturally occurring viral defense mechanism in bacteria. It works by binding the Cas9 enzyme to guide RNA, which can direct the Cas9 enzyme to a specific DNA sequence to make cuts in double-stranded DNA. Once the DNA is cut, the cell uses naturally occurring DNA repair mechanisms to rejoin the cut ends.

The CRISPR/Cas9 technology has been shown to result in unwanted off-target cutting, which means additional cutting at unintended sites that are often similar but not identical to the target DNA site. This off-target cutting can result in permanent mutations to the genomic DNA, which may unintentionally lead to detrimental mutations and oncogenesis, thereby creating significant safety concerns when used for the manufacture of cell and gene therapeutics.

Another popular site-specific gene editing platform used for cell and gene therapeutic applications are the Transcription Activator-Like Effector Nucleases, or TALENs. They are constructed by fusing a TAL DNA-binding domain to a DNA cleavage domain, typically FokI, which functions as an obligate homodimer, meaning two half-sites must come together at the exact same place and the exact same time in order to make a cut. Given the requirement for two half-sites, this type of system is sometimes called a fully dimeric system.

While TALEN technology can often cut specific sites in DNA with much higher fidelity than CRISPR/Cas9, it is relatively labor intensive and expensive to build. Conceptually similar, ZFN technology is a gene editing technology comprised of a class of DNA binding proteins used to make double-stranded breaks in DNA. Like TALEN technology, ZFN requires more preparation and work to use through the creation of arrays needed to target specific desired edits. TALEN and ZFN technologies both require activation of the cells to edit and do not work well in resting T cells, and thus fail to preserve a high percentage of the T<sub>SCM</sub> phenotype for CAR-T.

Another emerging gene editing technology is known as base editors. Base editing uses components from CRISPR systems together with other enzymes to directly install point mutations into cellular DNA or RNA without making double-stranded DNA breaks. DNA base editors comprise a catalytically disabled nuclease fused to a nucleobase deaminase enzyme and, in some cases, a DNA glycosylase inhibitor. Base editing technology is known to create some level of unwanted off-target mutations but the full extent is not yet known and could present a safety concern for allogeneic CAR-T where products could be given to many patients.

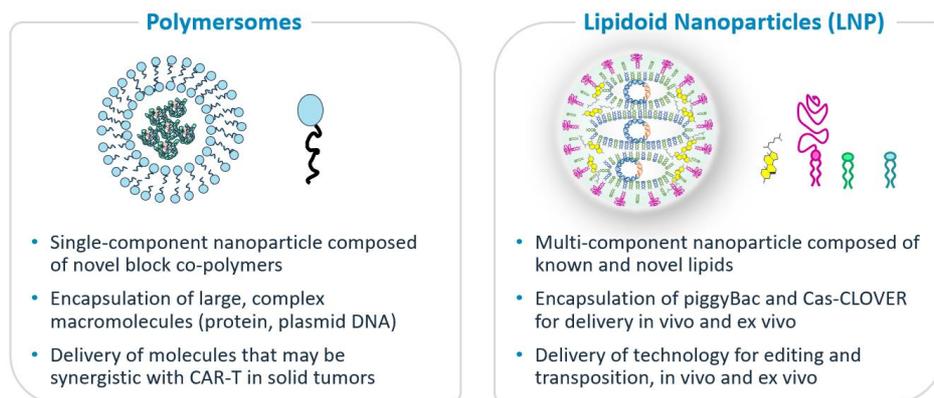
### **Gene Delivery Technologies: Nanoparticle Technology, In vivo and Ex vivo Electroporation and AAV**

In addition to our piggyBac platform for non-viral gene insertion and our Cas-CLOVER platform for gene editing, we have developed a set of platform technologies for gene delivery to allow us to deliver RNA, DNA and proteins into cells both *ex vivo* and *in vivo* for various applications. These technologies include nanoparticle technology, AAV technology and *ex vivo* and *in vivo* electroporation technologies and approaches. Because of the breadth of potential utility of piggyBac and Cas-CLOVER, we foresee a need for different delivery modalities for different applications.

In our autologous and allogeneic CAR-T product candidates, we edit the T cells *ex vivo* using electroporation to deliver the necessary piggyBac components required to stably insert the therapeutic transgene into the genome of the cells. In the case of our

allogeneic CAR-T product candidates, we also introduce Cas-CLOVER into the T cells via electroporation to edit the cells to eliminate alloreactivity.

In our initial liver-directed gene therapy programs, we are currently using AAV technology and lipid nanoparticles, or LNPs, to deliver piggyBac to the liver *in vivo*. We have developed a variety of distinct nanoparticle compositions to achieve different delivery objectives. These nanoparticles fall generally into two categories, polymersomes and LNPs. Polymersomes are single component particles comprised of novel block co-polymers and are designed to deliver large complex molecules such as proteins. LNPs are multi-component nanoparticles composed of known and novel lipids and are designed to deliver nucleic acids including mRNA and DNA. We are evaluating polymersomes to deliver therapeutic proteins that may be synergistic with our solid tumor CAR-T product candidates. We are evaluating LNPs to deliver both our piggyBac and Cas-CLOVER technologies.



Our longer-term goal for our nanoparticle platform is to be able to eliminate the need for AAV for *in vivo* gene therapies or *ex vivo* electroporation for *ex vivo* gene therapies by using nanoparticles to deliver our technologies into cells. We are also developing the technology and ability to deliver piggyBac and Cas-CLOVER through *in vivo* electroporation. While we have not yet nominated a product candidate using *in vivo* electroporation technology, we are exploring delivery of therapies to tissues that can be accessed from outside the body including skin, muscle and eye, which could open a range of potential development areas and new programs.

### CAR-T for Oncology: History of CAR-T

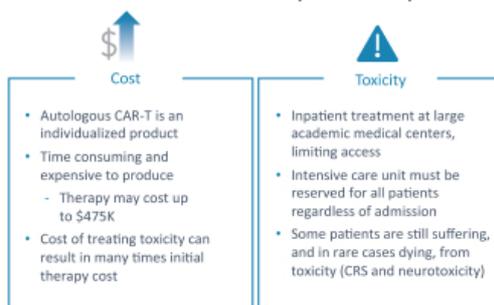
Until recently, all major treatment modalities for cancer shared the same problem: they killed cancer cells, but not without damaging healthy cells and tissues. Immuno-oncology, the concept of using the patient's own immune system to attack cancer, has the potential to eliminate this challenge. A person's adaptive immune system is responsible for recognizing and eliminating a number of threats to the body, such as infectious agents, as well as infected and abnormal cells. T cells, specialized white blood cells capable of detecting and killing infected and abnormal cells, are a crucial component of this adaptive immune response. CAR-T therapies work to redirect these T cells, which are extremely specific killers, to kill cancer cells through genetic modification.

CAR-T therapy has emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including those that have become heavily refractory to standard therapy. Currently, only autologous CAR-T therapy is commercially available, in which T cells are removed from the body, engineered with receptors specific to cell surface targets on the patient's tumor cells, and administered back into the body. Once the engineered T cells are administered, they are able to recognize and kill the tumor cells that express the target for the engineered receptor. We and others are now also developing allogeneic, or off-the-shelf, CAR-T therapies, in which a single donor or cell line is used to create a large number of doses of CAR-T, thereby greatly reducing the costs of manufacturing.

### The Challenges to Widespread Adoption of CAR-T

Despite the potent activity from early CAR-T entrants to the market, commercial adoption has been relatively slow to date. We believe that there are two main hurdles to widespread adoption of CAR-T. The first hurdle is cost. The therapies themselves can cost hundreds of thousands of dollars, and there are potentially significant additional costs from managing the occasionally substantial toxicities from the early-generation CAR-T therapies. The second hurdle is the toxicities themselves. While some progress is being made in managing the side effects, the risk remains significant for many patients, requiring that these early generation CAR-T

## The Two Main Hurdles for Widespread Adoption of CAR-T



We believe that our approach could enable us to address these hurdles to unlock the potential of CAR-T therapies. The combination of our higher percentage T<sub>SCM</sub> product and a potentially improved tolerability profile may allow us to move beyond academic medical centers and broaden the reach of these products. In our first clinical trial, P-BCMA-101, we were already dosing on a fully outpatient basis, following discussions with the FDA and after evaluation of our initial allogeneic programs, hope to implement the same approach. We believe outpatient dosing will enable expanded reach and lower cost. In addition, our booster molecule technology allows us to drive scale to our allogeneic manufacturing process, resulting from the ability to produce potentially hundreds of doses of our allogeneic CAR-T product candidates from a single manufacturing run from a single healthy donor. This dramatically reduces the manufacturing cost of CAR-T therapy to levels in the range of traditional biologic therapeutics in oncology and enabling off-the-shelf availability for immediate use.

### Addressing the Limitations of Early-Generation CAR-T Therapies

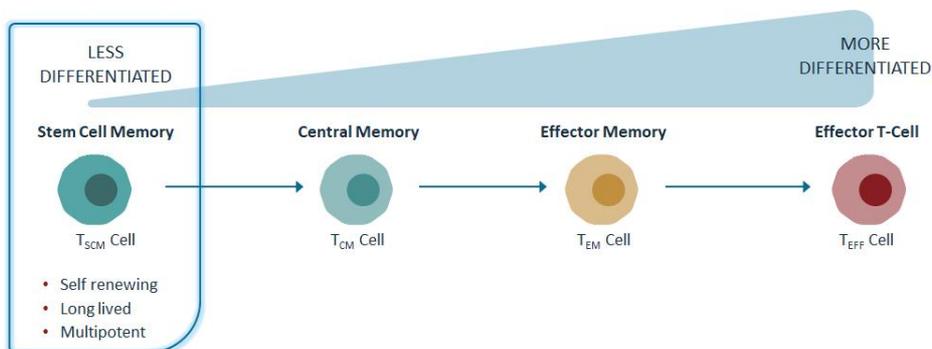
Although early-generation CAR-T therapy has shown significant potential, there are a number of limitations. The great majority of early-generation and current CAR-T therapies are produced using viral-based manufacturing. We believe that there are a number of inherent problems related to viral-based manufacturing that limit the potential of other CAR-T therapies. T cell engineering is typically achieved via viral transduction, the process of introducing foreign DNA into a cell using a virus, most notably with retroviruses, such as  $\gamma$ -retrovirus or lentivirus.

Despite extensive optimization of these viral vectors, their limitations are becoming more evident, including safety concerns regarding the insertional profile, limited genetic cargo capacity, and undesirable characteristics of the final product. We use our proprietary non-viral piggyBac DNA Delivery System to deliver CAR molecule genes to T cells. The most significant advantage of using a non-viral approach is the ability to generate CAR-T products comprised of a high percentage of T<sub>SCM</sub> cells. We believe this has the potential to result in therapies that elicit more consistent and durable responses with less toxicity. Additionally, we believe our non-viral approach will have much lower manufacturing costs and shorter manufacturing timelines. We have also developed allogeneic, or off-the-shelf, CAR-T therapies from healthy donors that will be potentially as good as or better than autologous CAR-T products, and be available off-the-shelf at a fraction of the cost of autologous therapies.

### Not all T cells are created equally

T<sub>SCM</sub> cells are believed to be ideal for cell therapy because they have the potential to engraft, be long-lived, self-renewing and multi-potent in that they can create wave after wave of more differentiated cells. There is a one-way maturation pathway from T<sub>SCM</sub> cells to central memory T cells, or T<sub>CM</sub>; then to effector memory T cells, or T<sub>EM</sub>; and lastly, to T<sub>EFF</sub> cells. As T cells mature and differentiate, their core functions and capabilities change, impacting their potency and durability. Our approach is to utilize a high percentage of less differentiated T cells in our product candidates with the goal of increasing persistence and mitigating some of the key limitations of early-generation CAR-T products. We also believe that creating a product with high T<sub>SCM</sub> may be why we are seeing such success in clinical efficacy for solid tumors where the T<sub>SCM</sub> cells can engraft and create wave after wave of cells to attack the tumor. Conceptually, products that are more matured and contain more effector cells are like a drug, whereas our products that have a high percentage of T<sub>SCM</sub> cells are like a prodrug. The T<sub>SCM</sub> cells do not kill tumor cells, they engraft and create the more differentiated cells that do the killing.

The following figure illustrates this one-way T cell maturation pathway, from T<sub>SCM</sub> cell to T<sub>EFF</sub> cell:



Based upon our clinical data to date, we have observed a strong correlation between the percentage of T<sub>SCM</sub> in the product candidate and best clinical response. In addition to our own experience, there is growing evidence and recognition that T<sub>SCM</sub> is correlated with efficacy in the clinic.

### CAR-T in Hematological Tumors

Early-generation CAR-T therapeutics have demonstrated an ability to achieve impressive responses in hematological malignancies, even in pre-treated patients who are relapsed and/or refractory to prior lines of standard therapies. Dramatically higher response rates than those reported for all prior therapeutics have been achieved in some indications, with some patients likely being cured. Despite these outcomes, however, significant challenges remain with regard to safety and cost. Furthermore, we believe additional improvements could be made with regard to duration of response as a number of patients have relapsed after receiving CAR-T therapy and duration of response has generally been poor.

A major limitation of early-generation CAR-T therapies is the potential for severe toxicity, most notably CRS and neurotoxicity, either of which can be fatal. Current CAR-T therapeutics are administered at large medical centers with ICUs so that an ICU can be reserved for all patients being administered CAR-T in the case they experience these severe toxicities. Furthermore, the cost of dealing with the toxicities associated with CAR-T can oftentimes exceed the cost of the therapeutic itself. There are also significant cost, manufacturing and commercial scalability challenges ahead for other CAR-T candidates, mainly due to the nature of viral-based manufacturing. These issues greatly limit the commercial reach of current CAR-T products. There are several potential reasons for the poor duration of response, which generally fall into two categories: elimination of the CAR-T cells from the body and loss of expression of a CAR-T target on a tumor cell, known as antigen escape.

### Safety

The excitement over the impressive responses seen initially with early-generation CAR-T approaches has unfortunately been tempered by potentially life-threatening toxicities, most notably CRS and neurotoxicity. Typical clinical symptoms of neurotoxicity include headache, confusion, delirium, language disturbance and seizures. As more is being understood about these toxicities, it is now appreciated that they may be caused by different molecular mechanisms. However, both are rooted in a T cell response that is essentially too rapid and too strong. The CAR-T cells and other immune cells of the patient release cytokines and other molecules that initiate immune cascades that can be fatal if not avoided or successfully treated.

T<sub>SCM</sub> cells express fewer cytotoxic effector molecules than more matured T cells and are postulated to differentiate and develop cytotoxic capability gradually. We believe the T<sub>SCM</sub> cell phenotype may lead to a more controlled expansion of CAR-T and more gradual killing of tumor cells, thereby lessening the severity of toxicities, such as CRS and neurotoxicity, and resulting in a CAR-T product that can be administered on a fully outpatient basis.

A second safety feature incorporated into our CAR-T product candidates is the positive selection for CAR-positive cells during the manufacturing process. Drug resistance genes have been employed in other cellular therapeutics as a mechanism for selecting and purifying gene-modified cells to improve the efficiency of gene therapy. Our product candidates are engineered to express a variant of the human dihydrofolate reductase, or DHFR, gene. Cells containing this variant of the DHFR gene are slightly resistant to the drug

methotrexate, or MTX. The advantage of DHFR over other drug-resistance strategies is that MTX is not genotoxic and preferentially kills dividing cells. Importantly, this gene-drug combination has been previously demonstrated to permit *ex vivo* selection of genetically modified T cells with relatively low concentrations of MTX.

Additionally, we enrich for gene-modified CAR-positive cells during *ex vivo* expansion, thereby purifying the therapeutic product and controlling for any patient-to-patient variability in raw material or manufacture, making our CAR-T product candidates essentially 100% CAR-positive. This contrasts with competing products that do not utilize positive selection and typically contain a significant number of CAR-negative cells that cannot kill cancer cells but are artificially activated and expanded outside of the body and may contribute to CRS and/or neurotoxicity. Thus, we believe that positive selection is another mechanism, in addition to the high percentage of T<sub>SCM</sub> cells, that may result in our CAR-T product candidates having a significantly greater therapeutic index.

Given that every CAR-T cell has a transgene, which is stably integrated into the genome, there is the possibility that the transgene delivery part of the CAR-T manufacturing process could create a detrimental mutation that allows the cell to expand in an uncontrolled manner, which can result in the cell itself becoming cancerous. Additionally, in the case of viral-manufacturing, some viral components that are integrated into the CAR-T cell as part of the transgene, such as the long terminal repeats, or LTRs, of the transgene may be able to activate a gene already in the cell, resulting in the cell becoming cancerous, a process called oncogenesis.

There has been an example of a clonal expansion in a patient who received a CAR-T product made from lentivirus. A clonal expansion means that a single T cell was given a proliferative advantage and was able to grow to a majority of all the CAR-positive cells in the patient. In this case, the clonal expansion was caused by the lentivirus inserting into a gene important for proliferation. Our CAR-T product candidates utilize our proprietary piggyBac technology. PiggyBac has shown low integration into intragenic regions, meaning that it is less likely to cause a detrimental mutation. Also, unlike retroviruses, piggyBac does not contain LTR sequences, but rather ITRs and other components which act as strong insulators, enhancing stable transgene expression and lowering risk of oncogenesis.

We have included a cellular safety switch in each of our product candidates as an additional safety mechanism. Both CRS and neurotoxicity are thought to be related to an overactive T cell response. Therefore, timely intervention to diminish the number of CAR-T cells should be an effective method of managing the majority of adverse events. We believe an ideal intervention technique is one that could be titrated such that not all CAR-T cells would be eliminated, leaving some for continued therapeutic effect.

#### *Commercial Scalability*

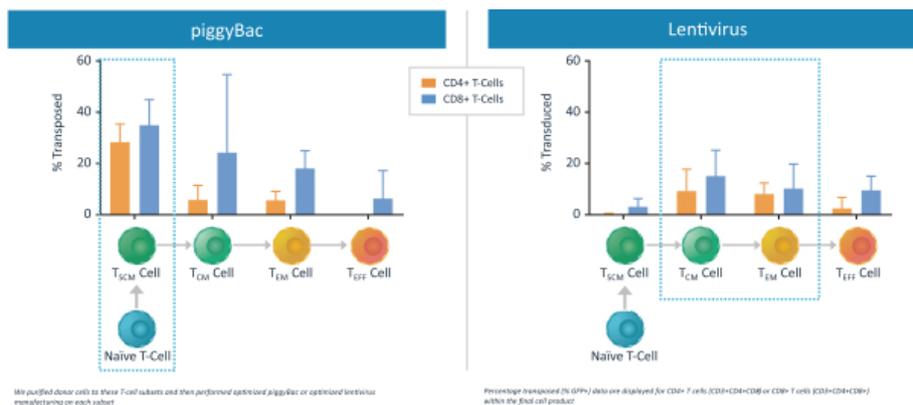
Another challenge with early-generation CAR-T products is their commercial scalability. Autologous CAR-T products are, by definition, individualized products. They are also typically expensive to produce, particularly when using viral-based manufacturing methods. We believe our non-viral piggyBac approach is more efficient and cost effective than historical CAR-T methods as it utilizes GMP nucleic acids, DNA and RNA, which are faster and cheaper to produce than GMP virus. We have further optimized the manufacturing process to eliminate some of the costly materials associated with the viral-based methods, including magnetic beads and cytokines.

CAR-T products that elicit severe and potentially fatal toxicities, such as CRS and neurotoxicity, require that the drug be administered in a tertiary care hospital where the physicians are familiar with treating these toxicities and where admission to an intensive care unit is an option. The potential for these severe toxicities currently precludes administration in community hospitals or outpatient infusion centers. In our dose-escalation P-BCMA-101 Phase 1 clinical trial, as of December 15, 2021, to our knowledge no patient has had to be admitted to intensive care units for CRS or neurotoxicity. Based on these results, and following discussions with the FDA, we were able to dose on a fully outpatient basis. As we evaluate initial findings on our P-BCMA-ALLO1 program, if we continue to see the same safety responses as we did in the autologous trial, we plan to pursue outpatient dosing as well.

#### *Efficacy Challenge: Elimination of CAR-T Cells*

There are numerous explanations as to why CAR-T cells are eliminated from a patient after administration, but we believe the primary explanation is that the majority of T cells in other CAR-T products are more matured and short-lived T cells, including T<sub>EFF</sub> cells. Not all T cells are created equally, and we believe the ability to develop a product that consists predominantly of early memory T cells, particularly T<sub>SCM</sub> cells, is the key to increasing duration of response and tolerability. Our non-viral piggyBac manufacturing method is the only commercially viable approach known to us that can create CAR-T products with a high percentage of the highly desirable T<sub>SCM</sub> cells with the efficiency of our technology.

In order to test the ability of our piggyBac DNA Delivery System to preferentially deliver CAR-containing transgenes to T<sub>SCM</sub> cells, we conducted a preclinical experiment in which we separated T cells into their various subtypes, then individually put those subsets through either an optimized piggyBac manufacturing process or an optimized lentivirus process and measured the percentage of transposed or transduced cells in each final product subset. As shown in the figures below, piggyBac was very efficient at transposing (the piggyBac process of delivering the CAR-containing transgene) in T<sub>SCM</sub> cells, while lentivirus was relatively ineffective at transducing (the lentiviral process of delivering the CAR-containing transgene) in T<sub>SCM</sub> cells. We measured both CD4+ T cells (also known as T helper cells) and CD8+ T cells (also known as cytotoxic T cells) which represent two subsets of T cells believed to interact and be important in immune function and T cell response.

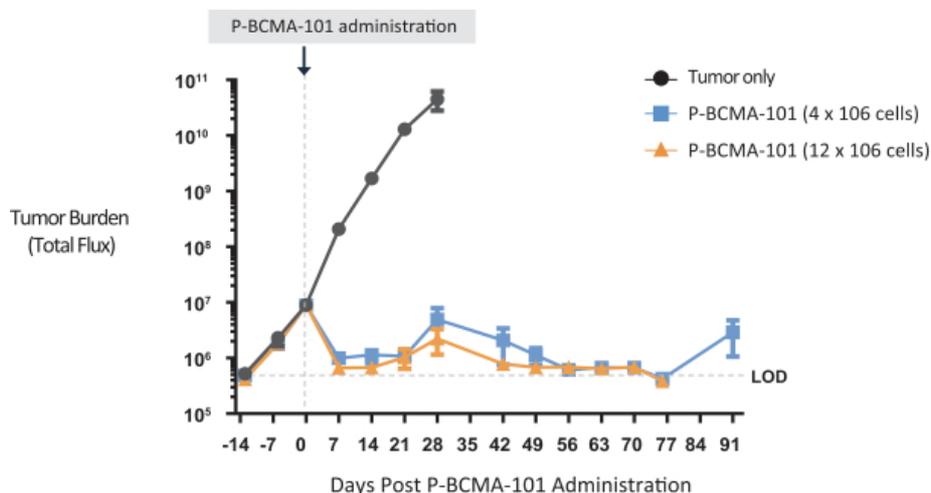


Given the one-way maturation pathway of T cells, we believe utilizing a genetic engineering method that preferentially modifies T<sub>SCM</sub> cells is essential for creating a final product with a high percentage of T<sub>SCM</sub> cells. During manufacturing, once we have completed the genetic modification step, we then perform a positive selection step to eliminate cells that have not been modified. Lastly, we activate and expand the remaining cells under conditions that favor self-renewal of T<sub>SCM</sub> cells without differentiation, resulting in a product that has a high percentage of T<sub>SCM</sub> cells, even when starting with patient material with a relatively low percentage of T<sub>SCM</sub> cells. Our non-viral piggyBac DNA Delivery System typically yields T<sub>SCM</sub> cell percentages reaching as high as 80%. We compared our piggyBac manufacturing method to a lentivirus-based manufacturing method that utilizes alternative media (Aim V, Thermo Fisher Scientific), different T cell stimulation (CD3/CD28 beads from Dynal/Thermo Fisher Scientific) and virus for vector integration (lentivirus). The sorted T cell subsets were put through the piggyBac process once in a pilot experiment with cells from one donor, and again in a comparison with the lentivirus process with cells from three donors. The early memory component, or combined T<sub>SCM</sub> and T<sub>CM</sub> cells, typically comprise greater than 90% of the cells of our product candidates. Notably, in December 2019, we were issued a U.S. patent that has claims that cover any modified T cell product that has 25% or more T<sub>SCM</sub> cells.

Others in the field of CAR-T development are also attempting to increase the percentage of T<sub>SCM</sub> cells in their products through alternative methods during the manufacturing process, including the addition of small molecule inhibitor drugs and various cytokines, reducing the time in culture, and physically enriching through sorting methods for early T cells. However, we believe these methods all have inherent problems that will limit the ability to successfully create a final product candidate with a high percentage of T<sub>SCM</sub> cells.

In both our own clinical data and in data published and presented by others, a higher percentage of T<sub>SCM</sub> cells in CAR-T products have been shown to correlate with clinical response, and our CAR-T product candidates contain a high percentage of T<sub>SCM</sub> cells. Our goal is that our product candidates will overcome the limitations of other CAR-T products in many respects, including potency and durability of response.

The importance of these T<sub>SCM</sub> cells can be seen in a preclinical model in which mice are implanted with a highly aggressive human multiple myeloma cell line (MM.1S). In this model, P-BCMA-101 engrafted with marked persistence *in vivo*, and remarkably, was able to control relapses without re-administration of product, as shown in the chart below:



We have also seen clinical evidence that our product candidates that are comprised of a high percentage of T<sub>SCM</sub> cells can engraft and persist for exceptionally long periods in some patients. As of November 16, 2020, one patient from Cohort 2 of the Phase 1 clinical trial for P-BCMA-101 had been in a durable response for greater than 30 months. In another patient from Cohort 3 of the same clinical trial, we have recently observed our CAR-T modified cells in the peripheral blood at over 2 years post infusion. Because T<sub>EFF</sub> cells are generally thought to live for a few weeks up to a few months, the presence of these cells in the patient's blood at 2 years is evidence that some number of T<sub>SCM</sub> cells have engrafted and continue to produce more differentiated cells to continue to fight the cancer.

More matured T cells, which already have a short lifespan compared with T<sub>SCM</sub> cells, can be eliminated from the patient due to their inability to persist, leading to poor efficacy of the product. One reason that premature loss of CAR-T occurs is the presence of CAR binding molecules on the surface of the T cell that can interact with each other. This results in crosslinking of the CAR molecule and a phenomenon called tonic signaling, in which the CAR-T cells are essentially always stimulated and active. Tonic signaling results in premature loss of efficacy, poor expansion and cell death, referred to as T cell exhaustion. We use binding molecules, such as Centyrins, heavy-chain-only antibody fragments and carefully selected single-chain fragment variable antibodies to minimize the risk of crosslinking and tonic signaling.

#### Efficacy Challenge: Antigen Escape and Antibodies

Some CAR-T products have been shown to lose efficacy due to what is called antigen escape, which occurs when expression of a CAR-T target on a tumor cell is lost or drastically reduced due to selective pressure from the CAR-T therapeutic, resulting in an expansion of the tumor cells that have escaped the ability of the CAR-T to kill them. To avoid antigen escape, we have focused our efforts on selecting targets where we believe expression is less likely to be reduced. For example, BCMA is important for cell proliferation, and so is considered less likely to be lost by the tumor cell following CAR-T treatment. Likewise, PSMA plays a key role in modulating signaling pathways implicated in mCRPC and so may also be less susceptible to antigen escape.

Another method to prevent antigen escape involves pursuing multiple targets on the cancer cell with the same CAR-T product. The likelihood that a cancer cell will be able to simultaneously downregulate or lose expression of multiple targets, as opposed to any single target, is greatly reduced. While the genetic cargo capacity of viral vectors is quite limited, piggyBac has demonstrated the ability to deliver greater than 20 times more genetic cargo capacity, allowing transfer of multiple CAR molecule genes simultaneously. We believe the large genetic cargo capacity of piggyBac could allow us to further address antigen escape by including two or more CARs or TCRs on the same T cell. We have several Dual CAR programs currently in preclinical development designed to seek improved efficacy including potentially addressing antigen escape in various indications.

In our P-BCMA-101 Phase 1 clinical trial, we observed that some patients have formed antibodies, also known as anti-drug antibodies in response to our treatment. This is not uncommon in biologic drug development, including CAR-T development. Based upon our data to date, it appears that anti-drug antibodies are more likely to form at higher dose cohorts. In our expanded Phase 1 clinical trial for P-BCMA-101 we investigated additional dosing strategies that may reduce or eliminate the impact of anti-drug antibodies, including administering the dose in smaller cycles over the first 30 days and adding rituximab to the preconditioning regimen to potentially suppress any antibody response. As presented at ASH in December 2021, the P-BCMA-101 arm using rituximab showed the absence of antidrug antibodies.

## **CAR-T in Solid Tumors**

### *Efficacy Challenge*

In addition to the standard concerns regarding persistence of T cells in the treatment of hematologic malignancies, there are factors that exacerbate this problem when using CAR-T products for the treatment of solid tumors. To date, the great majority of early-generation CAR-T products have not demonstrated significant responses in solid tumors and there are a number of potential explanations for this poor efficacy. First, it is possible that CAR-T cells have more difficulty accessing solid tumor cells. In some diseases, such as acute lymphoblastic leukemia, the tumor cells are easily accessible by the CAR-T cells. However, in most solid tumors, there are a number of factors that may make it more difficult for CAR-T cells to access the tumor. Second, it is possible that solid tumor cells have changes in expression of certain checkpoint genes that render them resistant to killing by T cells. Third, the center of many solid tumors is very hypoxic, or low in oxygen concentration, and this environment is not thought to be conducive to T cell function.

There have been a few exceptions to the poor efficacy of CAR-T in solid tumors, notably in glioblastoma multiforme and hepatocellular carcinoma, where treatment with CAR-T has led to complete responses, or a CR, in solid tumors. In these rare cases, the patient was treated with numerous administrations of CAR-T product. Though CAR-T cells are not as effective against solid tumor cells as they are against hematological tumor cells, this can potentially be overcome by giving multiple administrations of CAR-T, resulting in numerous waves of more matured T cells killing the cancer cells. This approach would be more viable if there were an unlimited number of cells with which to treat the patient. However, manufacturing early-generation CAR-T products is relatively time consuming and expensive, and the final product is comprised of a limited number of cells, thereby making this approach impractical for many patients.

All of our solid tumor product candidates, including P-PSMA-101 and P-MUC1C-ALLO1, are comprised of a high percentage of T<sub>SCM</sub> cells, which we believe are able to engraft, self-renew and mature into every T cell subtype, including the T<sub>EFF</sub> cells, which can persistently attack the tumor until deep responses are potentially achieved. Therefore, we believe our CAR-T product candidates have the potential to achieve high rates of response against solid tumors with a single administration. In early clinical results from P-PSMA-101, we have seen extremely promising efficacy. As reported on February 17, 2022, of the first 14 patients, 71% have seen a reduction of PSA, of which in 36% of patients saw a PSA reduction of greater than 50%. In addition, one patient demonstrated evidence of near complete tumor elimination as evidenced by PSMA PET and other markers.

### *Safety*

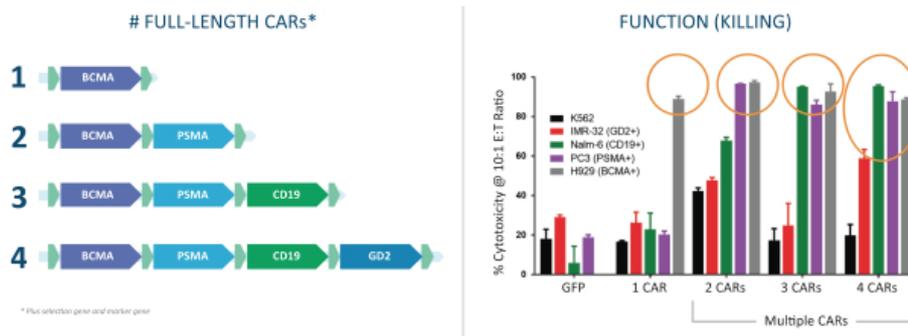
Our solutions for addressing CAR-T related toxicity concerns regarding CRS and neurotoxicity with respect to hematological tumors also apply to solid tumors. However, there are additional toxicity concerns for CAR-T products when administered to treat solid tumors. When compared to hematological tumors, solid tumors generally have fewer unique surface targets that are not also expressed on healthy cells, so greater care must be taken when choosing targets to avoid on-target/off-tumor toxicity, which occurs when a CAR-T cell recognizes the intended target on a healthy cell and kills that cell. We seek to address this risk by choosing targets that are overexpressed in cancer cells, such as PSMA and MUC1-C, and by using binding molecules that we believe are more effective at binding the cancerous form of the target.

In our P-PSMA-101 trial, we experienced a clinical hold early in the study to evaluate the death of a patient, which may have been related to treatment with P-PSMA-101 but also partially due to a patient noncompliance event. Following protocol amendments, the clinical hold was lifted and we have since dosed additional patients in the trial without experiencing additional patient deaths potentially related to treatment. As reported on February 17, 2022 at ASCO-GU, we observed CRS in 57% of patients, with 14% of patients experiencing Grade 3 or higher and observed immune effector cell-associated neurotoxicity syndrome (ICANS) in 14% of the evaluable patients.

As we expand our solid tumor CAR-T pipeline, we expect it to become harder to identify targets that are unique to the solid tumor cells. Therefore, we are developing sophisticated systems designed to direct a CAR-T cell to kill a tumor cell based on presence or absence of a combination of targets. For example, we believe that we can develop a CAR-T that will kill only tumor cells that have both target A and target B on their surface but will not kill normal cells with target A or target B singularly on their surface.

A related strategy is developing a CAR-T that will kill a cell only if it expresses target A and B (which may be present on both cancer cells and normal cells) but not target C (which may only be present on normal cells). All such strategies require the co-expression of more than two CAR molecules on the surface of the same CAR-T cell. We believe the piggyBac DNA Delivery System can enable these approaches due to its large genetic cargo capacity. In contrast, viral-based approaches are typically unable to deliver more than two full-length CAR molecules.

We have demonstrated that we can produce CAR-T cells that express up to four full-length CAR molecule genes, each with a different target specificity, along with two additional genes, using a single piggyBac transposon in manufacturing (left panel). We further demonstrated that, when expressed, all CAR molecules perform specific killing of corresponding cell lines that express the target (right panel):



Specific killing was evaluated via reporter-based killing assays where the indicated human tumor cells were genetically modified to express the luciferase gene. These tumor cells were co-cultured *in vitro* with CAR-T cells for 24 hours at a defined effector to target ratio of ten to one (10:1). The CAR-T cells expressed different combinations of full-length CARs: (1) BCMA CARTyrin, (2) BCMA CARTyrin and PSMA CARTyrin, (3) BCMA CARTyrin, PSMA CARTyrin and CD19 scFv-based CAR or (4) BCMA CARTyrin, PSMA CARTyrin, CD19 scFv-based CAR and GD2 scFv-based CAR. Cytotoxicity (specific lysis) was evaluated by adding luciferin substrate and reading luminescence signal and percent cytotoxicity was calculated by enumerating the luminescence of tumor cells alone versus tumor cells with CAR-T cells. Each individual CAR demonstrated cytotoxicity against its cognate antigen, even when expressed in the presence of three additional full-length CARs.

Another approach to treating solid tumors is to express a variation of a TCR that is specific for a cancer-associated protein that is only expressed inside of the cancer cell, in contrast to a CAR molecule that only recognizes targets on the surface of the cell. We believe we can use the TCR strategy in combination with the CAR strategy by expressing combinations of both CAR and TCR molecules on the surface of the same cell using the piggyBac manufacturing method.

#### Commercial Scalability

We believe each of the commercial and scalability benefits of our approach in hematological tumors would also apply to solid tumors.

#### Allogeneic or Off-The-Shelf CAR-T Therapies

##### Efficacy Challenge

The goal of an allogeneic, or off-the-shelf, CAR-T product is to create a large number of doses of CAR-T from a single donor or cell line. A successful allogeneic CAR-T product could be used as an off-the-shelf product to treat any patient with a specific indication, thereby greatly decreasing the costs associated with manufacturing. However, if an allogeneic product requires high doses or multiple doses in order to achieve the same activity as a similar autologous product, then many of the potential cost-saving advantages of an allogeneic product would not be realized.

Gene editing tools are widely used to eliminate expression of certain cell surface molecules, which may be used to avoid the potential reactivity of donor cells against the patient, which results in graft-vs-host disease, or GvHD, as well as the reactivity of the patient's cells against the CAR-T product, a reaction called host-vs-graft. We believe it is imperative to use gene editing tools that can efficiently edit resting T cells when creating an allogeneic CAR-T product, as activating T cells will initiate the maturation pathway.

Once T cells begin maturing, they start to lose their desirable T<sub>SCM</sub> characteristics and thereby become exhausted, rendering the resulting product less efficacious.

Unlike many other gene editing technologies, Cas-CLOVER can efficiently edit resting T cells, allowing for the maintenance of the highly desirable T<sub>SCM</sub> product composition in allogeneic product candidates, an important component of our CAR-T approach. Our goal with all of our allogeneic product candidates is to create a product with a profile comparable to or better than an autologous version of the same product; in the case of our first fully allogeneic product candidate for multiple myeloma, P-BCMA-ALLO1, our efficacy benchmark will be against P-BCMA-101 and other BCMA targeting programs.

### *Safety*

In addition to the standard concerns regarding CRS and neurotoxicity, there are additional safety concerns relative to an allogeneic product. As mentioned above, an allogeneic product can cause two forms of alloreactivity: GvHD and host-vs-graft. Host-vs-graft is concerning only in that it may cause premature elimination of the allogeneic CAR-T cells, resulting in all of the previously discussed efficacy challenges related to poor persistence of product, but it does not create a safety concern.

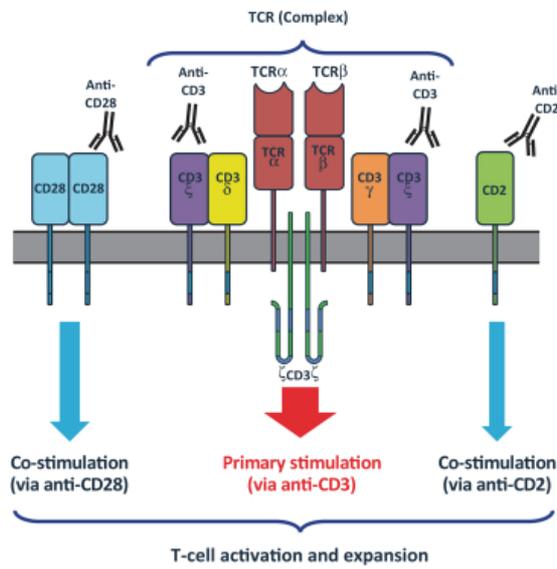
However, GvHD, a situation where the CAR-T cells are killing the healthy cells of the patient, is a serious and potentially fatal condition. Studies have suggested that the endogenous TCR is the molecule that needs to be eliminated in order to prevent GvHD. If this molecule is not completely eliminated in nearly 100% of CAR-T cells, then GvHD may become a problem. Our highly efficient Cas-CLOVER technology and subsequent purification step has resulted in cells that have TCR expression completely eliminated from at least 99% of the cells, a level we believe to be safely above that required to prevent GvHD.

An advantage of an allogeneic product is that many doses can be generated from a single individual donor or cell line. However, a potential disadvantage is that any detrimental mutation created during manufacturing would be potentially present in doses given to many patients, as opposed to an autologous product where this risk is limited to the individual patient. Therefore, it is especially important to minimize or completely prevent unwanted off-target mutations. It is well known that some gene editing technologies, such as CRISPR, have the possibility of creating unwanted mutations. In preclinical testing, our Cas-CLOVER technology has shown precise site-specificity, having no or very little propensity for creating off-target mutations. Based on our own preclinical data and previously published results on other fully dimeric CRISPR systems, we believe Cas-CLOVER is the most specific gene editing method available.

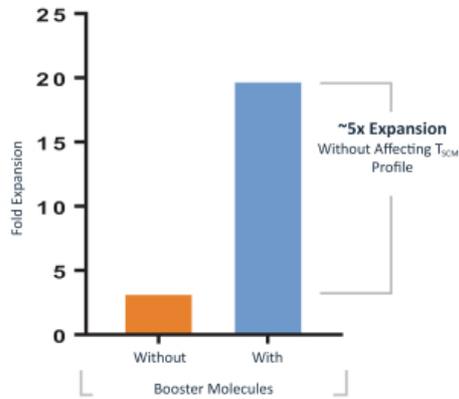
### *Commercial Scalability*

A fully allogeneic CAR-T product would offer the possibility of significant time and cost savings in manufacturing, thereby greatly decreasing the cost per dose and increasing patient accessibility. Nonetheless, a manufacturing process must still be run on individual donor or cell line material in order to create a fixed number of doses of an allogeneic product. One of the most expensive parts of a manufacturing run for viral-based manufacturing methods is the virus itself. The piggyBac manufacturing system uses only GMP DNA and RNA without the need for GMP virus. We believe this will result in product candidates that are significantly cheaper to produce, even in the context of an allogeneic CAR-T product. Furthermore, the development and manufacturing timelines for piggyBac are shorter than those for virus, meaning one can move from product concept to GMP material more quickly. As an example, we moved P-BCMA-101 from product concept to the first patient dosed in a clinical trial in less than two years, and we believe we can apply these learnings to meet or exceed these timelines for future product candidates.

Genetic modification of the TCR, necessary to avoid GvHD as discussed previously, creates T cells that may be difficult to expand during the manufacturing process. TCR is commonly used as a key receptor for T cell stimulation in most autologous CAR-T manufacturing strategies. However, in allogeneic strategies, knockout of any single component of the TCR causes loss of the entire TCR complex from the surface of the engineered T cell, thereby significantly reducing its responsiveness to anti-CD3 antibodies during manufacturing. These consequences of eliminating the TCR and other genetic modifications have been commonly referred to as the "Allo Tax." The TCR complex is depicted in the figure below.



We have developed proprietary booster molecules that have the potential to overcome this issue, while retaining and potentially increasing the percentage of T<sub>SCM</sub> cells in the final product. Booster molecules are an RNA-based technology introduced to T cells during the manufacturing process, which results in transient expression of a receptor on the surface of T cells that allows the cells to respond to antibody-based activator molecules, resulting in significant expansion of the cells without causing maturation or exhaustion of the cells. The use of a proprietary booster molecule resulted in enhanced expansion and yield, resulting in the production of more than five-fold the number of cells than without the booster molecule from a single manufacturing run (see figure below).



We believe that we can create fully allogeneic product candidates, such as P-BCMA-ALLO1, P-PSMA-ALLO1 and P-MUC1C-ALLO1, that retain a profile that is comparable to their corresponding autologous products, as applicable, but with the ability to create enough doses to potentially treat hundreds of patients from a single manufacturing run.

#### Our CAR-T Product Candidate Pipeline

We believe we are particularly well-positioned to drive the continued advancement of CAR-T therapies in oncology. Our proprietary non-viral, gene engineering technologies are designed to address some of the greatest challenges to the successful

implementation and commercialization of CAR-T therapies. We have built a wholly owned pipeline of autologous and allogeneic CAR-T product candidates, initially focused on the treatment of hematological malignancies and solid tumors.

### ***P-PSMA-101: Autologous CAR-T for metastatic castrate resistant prostate cancer***

#### *Overview*

P-PSMA-101 is a solid tumor autologous CAR-T product candidate being developed to treat mCRPC. P-PSMA-101 targets cells that express PSMA, which is highly expressed on mCRPC cells. PSMA is involved in folate uptake and is thought to confer a proliferative advantage to PSMA-expressing tumor cells. Additionally, PSMA levels increase as tumor cells become androgen-independent, a hallmark of advancing prostate disease. Therefore, we believe that PSMA may be less susceptible to antigen escape. P-PSMA-101 is currently being evaluated in a Phase 1 clinical trial.

The piggyBac transposon transgene of the P-PSMA-101 product candidate differs from P-BCMA-101 only in the binding (Centyrin) portion of the CAR molecule used, which we believe helps to reduce development and manufacturing risk by leveraging the experience gained with P-BCMA-101. As with P-BCMA-101, P-PSMA-101 includes a DHFR gene used to manufacture a highly purified product. Also, as with P-BCMA-101, P-PSMA-101 is produced with our proprietary manufacturing system that results in a highly purified product with a cell composition comprised of a high percentage of T<sub>SCM</sub> cells, with the goal of conveying numerous benefits over other CAR-T products manufactured using viral methods.

#### *Target Indication*

Prostate cancer is the fourth most common cancer globally and the second leading cause of cancer death among men in the United States, with a 60% occurrence rate in men over the age of 65. In the United States alone, there are approximately 2.8 million men living with prostate cancer, with approximately 40,000 new cases of mCRPC estimated each year. The majority of prostate cancer patient deaths in the United States are due to mCRPC.

Treatment paradigms for prostate cancer vary based on the age of the patient at the time of diagnosis. Typical early treatment options for prostate cancer range from active surveillance, radiation therapy, cryotherapy, immunotherapy, hormone therapy and surgical treatment. For metastatic disease, the paradigm bifurcates between hormone naïve disease and castrate resistant prostate cancer, or CRPC. CRPC cases are typically treated with the chemotherapy drug docetaxel, and a choice of abiraterone, enzalutamide, cabazitaxel and/or Radium-223. Typically, none of these therapies are curative.

Although five-year survival rates for patients with early prostate cancer are nearly 100%, a high unmet need for mCRPC remains, with a five-year survival rate of only approximately 30%. We believe P-PSMA-101, if successful in the clinic and approved, could dramatically increase survival, as well as quality of life for mCRPC patients.

#### *Clinical Development Strategy*

We filed an IND in late 2019 and received authorization to proceed to clinical trials in early 2020. We dosed our first patient in May 2020 and resumed enrollment in November 2020 following the clinical hold on the program from August 2020 to November 2020. Enrollment continued after approval of a protocol amendment intended to increase patient compliance and safety that includes modified inclusion and exclusion criteria and frequency of monitoring and laboratory testing. The current Phase 1 protocol allows for enrollment of up to 40 adult subjects with mCRPC across four arms of up to five dose escalation cohorts each, using a standard 3 + 3 dose-escalation design. Eligible subjects who enroll in the trial undergo leukapheresis to collect T cells for P-PSMA-101 manufacturing. Before administering the P-PSMA-101 product candidate, subjects receive a conditioning lymphodepletion chemotherapy regimen. In the first arm, the regimen will be 300 mg/m<sup>2</sup> of cyclophosphamide and 30 mg/m<sup>2</sup> of fludarabine intravenously daily for three consecutive days, followed in two days by a single infusion of P-PSMA-101. In a second arm, rituximab is added to the lymphodepletion regimen. The remaining two arms utilize these same lymphodepletion regimens, but multiple infusions of P-PSMA-101 will be administered in two-week intervals, and the lymphodepletion regimen may be repeated every six weeks twice more. Patients will then be assessed for safety and efficacy for up to 15 years. Part 2 of the trial will involve expansion of selected cohorts to further characterize outcomes for a potential recommended Phase 2 dose. A Phase 2 pivotal part or additional exploratory cohorts may be added to the trial depending on the initial findings.

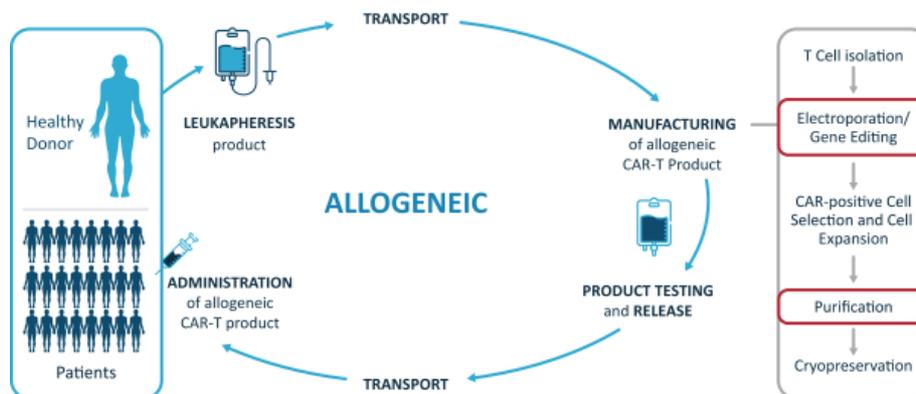
### ***P-BCMA-ALLO1: Allogeneic CAR-T in Multiple Myeloma***

#### *Overview*

P-BCMA-ALLO1 is a fully allogeneic CAR-T product candidate being developed to treat multiple myeloma. We received clearance from the FDA on our IND filing in the second half of 2021 and initial data from our Phase 1 clinical trial is expected in the second half of 2022.

P-BCMA-ALLO1 is our first fully allogeneic CAR-T product candidate derived from healthy donor cells, giving it the potential to be used as an off-the-shelf therapy for unrelated multiple myeloma patients. We believe our technology and manufacturing processes are ideally suited to develop allogeneic CAR-T product candidates with reduced alloreactivity and without unwanted mutations. We use our proprietary Cas-CLOVER gene editing tool to genetically engineer T cells in order to reduce or eliminate both GvHD and host-vs-graft alloreactivity. Cas-CLOVER is designed to efficiently edit resting T cells and has demonstrated precise specificity, thereby limiting unwanted off-target mutations and helping to improve tolerability. P-BCMA-ALLO1 also includes a single chain VH BCMA binder that we believe based on preclinical data is better than the binder that was part of our P-BCMA-101 program.

The manufacturing process for P-BCMA-ALLO1 shares characteristics with P-BCMA-101, differentiated only by the process of a multiplexed gene editing step and a purification step. Both product candidates include a DHFR gene used to manufacture a highly purified product that is essentially 100% CAR-positive.



We believe an allogeneic product with a profile similar to an autologous product would have significant advantages in terms of cost and commercial reach, with the ability to treat potentially hundreds of patients from a single manufacturing run.

#### Target Indication

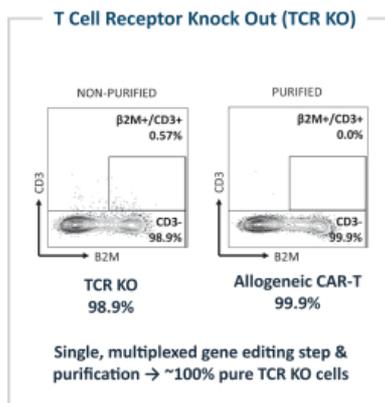
Multiple myeloma is a deadly form of blood cancer that develops from abnormal plasma cells, a type of immune cell that is typically responsible for secreting antibodies to fight infection. The underlying cause of multiple myeloma is unknown, but it affects patients by creating abnormal plasma cells that secrete high levels of antibodies, or fragments of antibodies, resulting in kidney and other organ malfunction that is ultimately fatal. It can also cause overproduction of abnormal plasma cells in the blood and tumor masses called plasmacytomas in the bone marrow or soft tissue.

There are approximately 100,000 patients suffering from multiple myeloma in the United States, with 30,000 new cases and nearly 13,000 deaths from the disease annually. It occurs more commonly in men than in women, typically affecting older adults, with the average age of onset of approximately 66 years. The current treatment paradigm in multiple myeloma begins with chemotherapy, proteasome inhibitors and immunomodulatory imide drugs, or IMiDs. The great majority of patients become refractory to these drugs and/or relapse, creating a high unmet need for treatments for relapsed/refractory patients. After failing proteasome inhibitors and IMiDs, patients typically resort to intensive chemotherapy regimens, with or without autologous stem cell transplant, or move to palliative care. Multiple myeloma is rarely cured, with the great majority of patients dying from the disease. Without treatment, the typical life span of a multiple myeloma patient is approximately seven months, while approximately half of those treated under the current regimens survive for five years after diagnosis. We believe P-BCMA-ALLO1, if successful in the clinic, can dramatically increase survival, as well as quality of life for relapsed/refractory multiple myeloma patients.

#### Preclinical Data

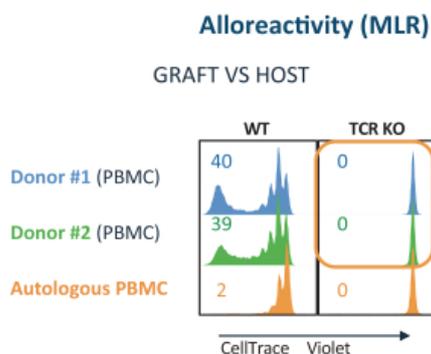
In our preclinical studies for our allogeneic product candidates we undertake gene editing to evaluate our ability to address both graft-vs-host and host-vs-graft reactions. We used our proprietary Cas-CLOVER gene editing platform, which has the ability to multiplex and efficiently edit resting T cells, to eliminate expression of cell surface proteins that are responsible for alloreactivity in a single gene editing step, followed by a purification step.

The figure below demonstrates our highly efficient gene editing to disrupt the T cell receptor  $\beta$  chain (TCR $\beta$ ) gene. In the experiment represented below, complete elimination of all TCR expression occurred in over 90% of cells with a single gene editing step and, after a single purification step, we were able to achieve a product candidate with >99.9% of cells with a TCR knockout. For P-BCMA-ALLO1, we also address host-vs-graft alloreactivity in the same multiplexed gene editing step by disrupting the Beta-2 Microglobulin gene (MHC1). With a single gene editing step we typically eliminate approximately 50-60% of MHC1. For P-BCMA-ALLO1 we do not purify for MHC1 knockout so that the final product is on average approximately 60% MHC1 knockout and >99.9% TCR knockout.



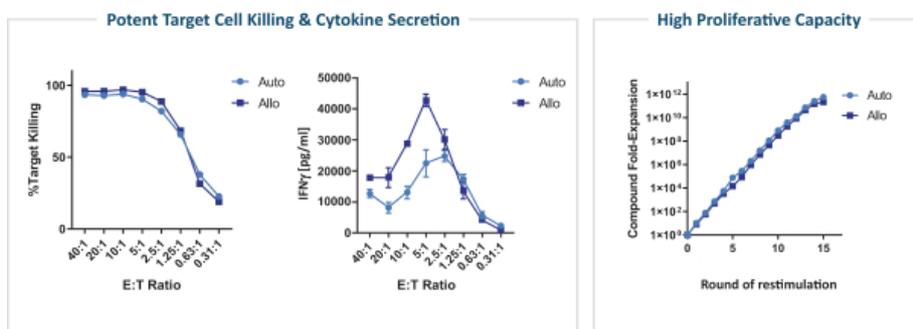
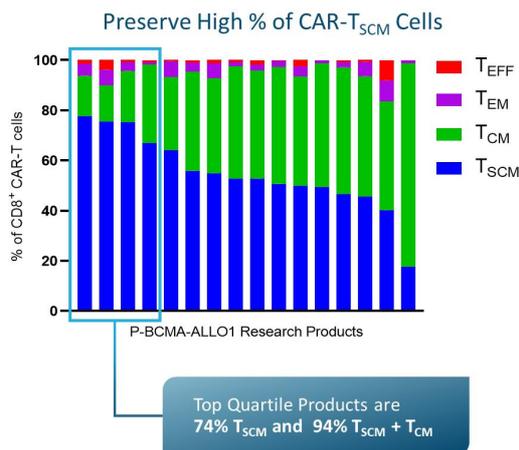
\*Data presented at ASH 2017

Multiple preclinical experiments demonstrate the potential of P-BCMA-ALLO1 to reduce or eliminate alloreactivity. The below figure represents an experiment for graft-vs-host alloreactivity, which is normally mediated by the intact TCR. The panel shows results of a mixed lymphocyte reaction, or MLR, where alloreactivity was demonstrated by a peak forming on the left-hand side of the graph. Peaks were clearly seen when non-genetically modified cells, or wild type, or WT, were mixed with cells from an unrelated donor, but not when mixed with cells from the same donor. Alloreactivity was eliminated when testing the P-BCMA-ALLO1 cells.



The cells used in MLR assays were WT cells or TCR KO cells, and peripheral blood mononuclear cells, or PBMC, from either the same donor (Autologous PBMC) or PBMC from allogeneic donors (Donor #1 and Donor #2). These cells were labeled with one of two cytosolic dyes: CellTrace Violet for the WT or TCR KO cells. A portion of each labeled cell type was irradiated (3,000 rads) to arrest proliferation and possibly increase immunogenicity. GvHD reactions were modeled by co-culturing non-irradiated WT or TCR KO cells with irradiated PBMC. In the 12-day proliferation MLR assay, the response of the non-irradiated cell type was assessed by flow cytometry and visualized as histograms in which the undivided cells retain high levels of cytosolic dye and thus appear on the right-hand side of the histogram and those cells that have undergone a proliferative response will dilute the cytosolic dye with each division, thereby appearing in peaks shifted to the left. Cells that have divided more than six times are beyond the sensitivity of this experiment and accumulate in one peak on the far left of the histogram. The frequency (average, n=4) of the cells with fully diluted cytosolic dye appears above the histogram in each panel.

One of our goals for our P-BCMA-ALLO1 product candidate is to preserve the same high percentage of T<sub>SCM</sub> cells in the final product that we have observed with our P-BCMA-101 and solid tumor autologous product candidates. Sixteen representative research-scale manufacturing runs for P-BCMA-ALLO1 resulted in high levels of T<sub>SCM</sub> as shown in the figure below. The top quartile contained a mean of ≥74% T<sub>SCM</sub> and 94% total memory cells (T<sub>SCM</sub> + T<sub>CM</sub>) of CD8<sup>+</sup> cells. In addition, a mean of ≥ 90% early memory (T<sub>SCM</sub> + T<sub>CM</sub>) has been observed for 15 of the 16 products.

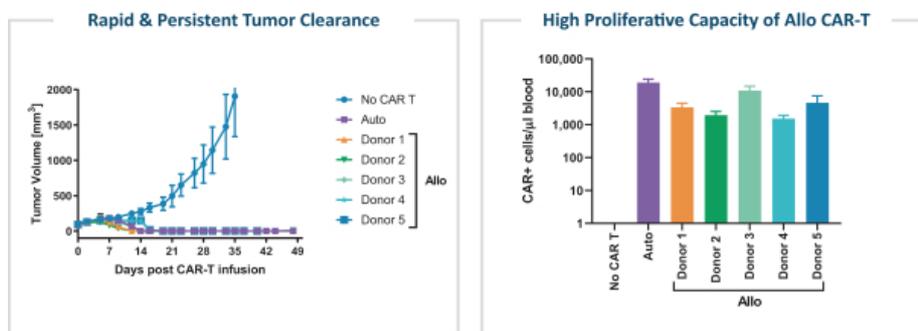


Further, as shown in the figures above, we have demonstrated that in preclinical models P-BCMA-ALLO1 had comparable intensity and specificity of killing target cells as an autologous version, equal or better cytokine secretion, as well as equivalent proliferative capacity.

Cytotoxicity was measured in a standard in vitro killing assay. Primary healthy donor human T cells were taken through one of two production processes: Autologous, or Auto, cells were generated using the P-BCMA-101 production process and allogeneic, or Allo, cells were generated using the P-BCMA-ALLO1 manufacturing process. The two T cell products were mixed at effector to target ratios shown with target cells that were BCMA-positive. In this assay, both target cell lines also express the luciferase protein and the amount of live and intact target cells in culture can be indirectly assessed as a function of the luciferase enzyme that they contain. After 48 hours of co-incubation, cytotoxic activity by the T cell products is evident as a decrease in the amount of live and intact target cells and expressed as data normalized to the same value for target cells cultured alone (i.e., 0% cytotoxicity is seen without T cells). The data above demonstrated that Auto and Allo were specific in killing the BCMA-positive cell lines. Moreover, the specific killing increased with higher effector to target ratios and the fact that both Auto and Allo products demonstrated virtually identical trends at each effector to target ratio indicates that both products have similar intensity and specificity of killing.

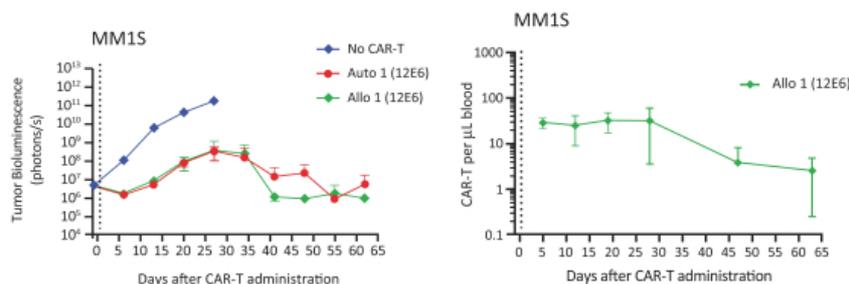
In the panel on the right in the figure above, proliferative capability of both Auto and Allo were assessed in an *in vitro* serial restimulation assay. Auto (CD3+) or Allo (CD3-) CAR-T cells, as described above, were thawed and then stimulated every 4-5 days with irradiated RPMI-8226 tumor cells which express the CAR target antigen, BCMA. At each stimulation, CAR-T cells were counted and reseeded with target cells at a 2:1 effector to target ratio. This assay demonstrates that CAR-T cells, both autologous and allogeneic, made with piggyBac have a high proliferative capacity and are able to expand to high cell numbers in response to tumor antigen. Importantly, it also shows that loss of the TCR complex in our P-BCMA-ALLO1 production process does not negatively affect the ability of our CAR-T cells to proliferate in response to antigen as our allogeneic cells could expand to a similar extent and for a similar length of time as CD3-replete autologous CAR-T product cells.

We also have demonstrated that P-BCMA-ALLO1 performs equal to or better than an autologous BCMA product generated from a healthy donor in an *in vivo* mouse model. As noted in the left panel of the figure below, we took five random healthy donors to generate P-BCMA-ALLO1 (Donor 1 to Donor 5) and compared those allogeneic products to an autologous BCMA CAR-T product produced from a healthy donor. As shown, all of the allogeneic products performed at least as well as the autologous product. In the panel on the right, we also compare the proliferative capacity of P-BCMA-ALLO1 to an autologous BCMA CAR-T product produced from a healthy donor.

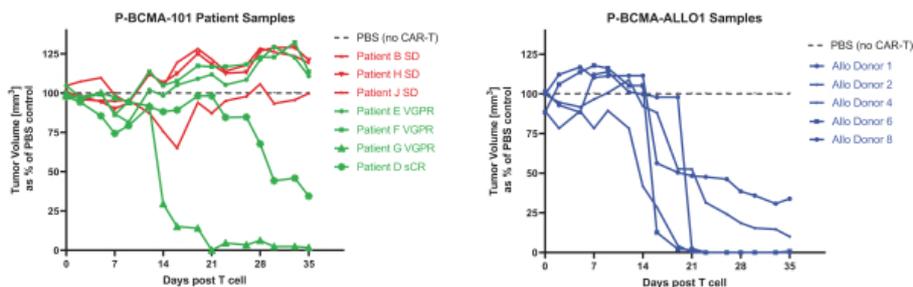


P-BCMA-ALLO1 exhibited potent anti-tumor effects in an *in vivo* mouse model of multiple myeloma. P-BCMA-ALLO1 was tested in alongside with healthy donor non-edited cells (Auto, CAR-positive/TCR-positive) in an *in vivo* model of multiple myeloma tumor control. Immunocompromised mice were implanted subcutaneously with  $1 \times 10^7$  RPMI-8226 BCMA+ tumor cells and tumors were established for 7 days before injection with  $1 \times 10^7$  CAR-T cells. P-BCMA-ALLO1 exhibited potent and sustained anti-tumor efficacy that was comparable to non-edited control CAR-T cells. P-BCMA-ALLO1 also demonstrated robust *in vivo* proliferation that could be detected in the blood of treated animals by Day 14 after T cell administration. The peak of expansion (Day 14) correlated with the timing of tumor control observed and was similar to expansion levels observed for TCR-positive autologous CAR-T cells.

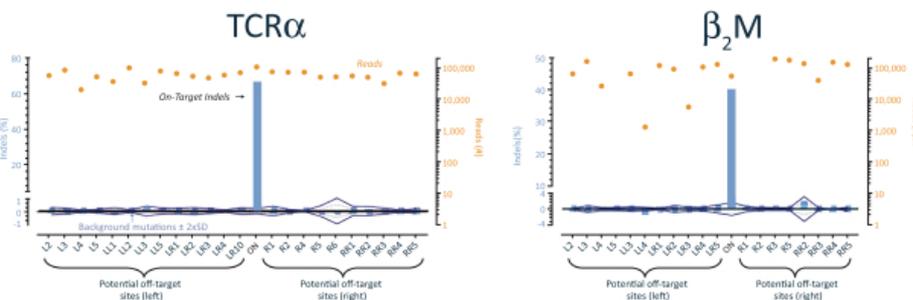
P-BCMA-ALLO1 also exhibited potent anti-tumor effects in an *in vivo* mouse model of multiple myeloma known as the MM1S model shown in the figure below. MM1S is an aggressive model of relapsed/refractory multiple myeloma where relapses after initial control of the tumor can be observed. Immunocompromised (NSG) mice were implanted intravenously with  $3 \times 10^5$  MM1S tumor cells and tumors were established for 7 days before injection with a standard dose of  $12 \times 10^6$  CAR-T cells. P-BCMA-ALLO1 (Allo) exhibited potent and sustained anti-tumor efficacy that was comparable to non-edited control autologous CAR-T cells (Auto) at the same single dose. P-BCMA-ALLO1 also showed persistence in this model as cells could be detected in the blood of treated animals at greater than 60 days post-CAR-T cell administration.



In addition, we have demonstrated that P-BCMA-ALLO1 performs equal to or better than autologous P-BCMA-101 products generated from cancer patients in an *in vivo* mouse model with a very high positive predictive value for how a product candidate will perform in the clinic. In the same mouse model (figure below), we used five random healthy donors to create P-BCMA-ALLO1 and compared those allogeneic products to seven P-BCMA-101 patient products, representative of patients that responded well (green; VGPR or sCR) or did not respond (red; SD) in the clinic. As shown, all the allogeneic products performed at least as well as the P-BCMA-101 products that resulted in either a VGPR or sCR in the clinic. Two of the four P-BCMA-101 products that demonstrated favorable outcomes in the clinic were able to control tumor in the mouse model. None of the three P-BCMA-101 patient products that resulted in SD in the clinic were able to control tumor in the mouse model.



Key to the creation of an allogeneic product is the specificity of the gene editing, without causing unwanted cuts or mutations in the DNA. Importantly, we demonstrated that Cas-CLOVER exhibited a high degree of specificity for on-target cutting during the cutting of gene targets in the production of P-BCMA-ALLO1. We performed deep sequencing of numerous top-ranked predicted off-target sites corresponding to these gene targets, and we did not observe any evidence of off-target activity:

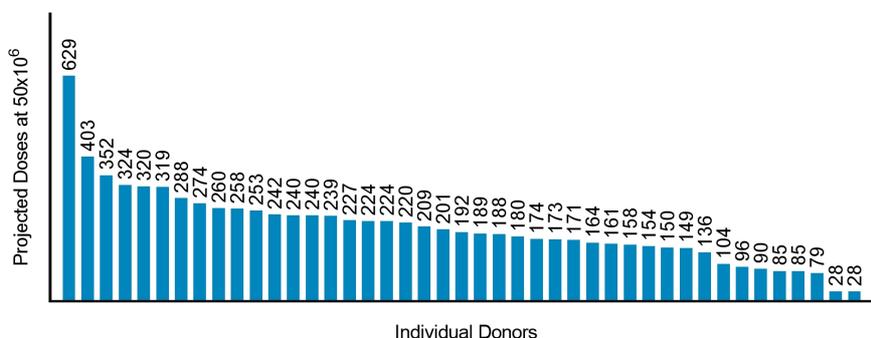


Cas-CLOVER can be used to efficiently knock-out several human T cell surface marker genes, such as TCR $\beta$  and  $\beta$ -2 Microglobulin ( $\beta$ 2M). To determine the level of off-target activity by Cas-CLOVER, next generation sequencing was used to investigate T cells gene-edited for TCR $\beta$  or  $\beta$ 2M genes. To do so, an algorithm was designed to predict all potential off-target sites of high DNA homology throughout the whole human genome for Cas-CLOVER gRNA. As Cas-CLOVER functions as an obligate homodimer, there are several hypothetical possibilities of dimer formation including left (L) gRNA + right (R) gRNA heterodimer, L + L and R + R homodimers, as well as L only and R only. On-target site and the top predicted off-target site amplicons from the above five different hypothetical combinations were PCR-amplified and the amplicons were analyzed using the Illumina Mi-Seq platform for deep sequencing with approximately 30,000 to 100,000 coverage at each locus for the identification of insertions and/or deletion, or indels.

In the above figure, the right Y axis shows the deep sequencing coverage rate at each locus, whereas the left Y axis shows the percentage of indels. The dotted lines show the level of background mutation in the absence of gene editing while the solid line shows the 2 standard deviation error bar of the control. The bars show the percentage of indels of all on- and off-target sites. These data show that the indels resulting at predicted potential off-target sites of high DNA homology are within the range of the background mutation rate of the non-edited negative control. Thus, next generation sequencing data confirmed that gene editing only occurs at target sites. Next generation sequencing data further showed that there is no off-target editing among the top predicted off-target sites.

We have developed proprietary booster molecules, which are an RNA-based technology introduced to T cells during the manufacturing process, results in transient expression of a receptor on the surface of T cells that is designed to allow the cells to respond to antibody-based activator molecules, resulting in significant expansion of the cells without causing maturation or exhaustion of the cells. Using booster molecules, we believe we can expand P-BCMA-ALLO1 cells to large numbers without losing any of the desirable cell attributes shown previously. In a preclinical study, we measured cell expansion of allogeneic CAR-T cells with and without the use of a booster molecule, and observed an approximately five times greater expansion during a single manufacturing run with the booster molecule, when compared to a manufacturing run without using a booster molecule. We continue to improve the booster molecule technology and other allogeneic manufacturing technologies and believe we will be able to significantly increase the number of doses generated per allogeneic manufacturing run in the future.

We estimate that we will be able to generate enough cells from a single full-scale manufacturing run to treat dozens to hundreds of patients. Forty-three research lots produced from 750M starting cells from random healthy donors and put through our near clinical-scale manufacturing process resulted in between 28 and 629 doses, as shown below. The number of doses was extrapolated based on projected yield from a full-scale manufacturing run using 2500M starting cells and projected dose of 50 million ( $50 \times 10^6$ ) cells per dose. We will continue to further optimize manufacturing and to identify donor characteristics that could be predictive of better performance.



### Clinical Development Strategy

The primary objectives of the Phase 1 clinical trial are to evaluate safety and any dose limiting toxicities, or DLTs, and determine the maximum tolerated dose, or MTD, of a single-dose infusion of P-BCMA-ALLO1 in adult patients with multiple myeloma who are relapsed and/or refractory to conventional therapy. In addition, we are assessing anti-myeloma response activity using the International Myeloma Working Group, or IMWG, criteria.

We are initially focused on enrolling patients with relapsed/refractory multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor, an IMiD, and anti-CD38 therapy, and/or who are refractory to a proteasome inhibitor, an IMiD, and anti-CD38 therapy.

We received clearance from the FDA on our IND filing in the second half of 2021 and initial data from our Phase 1 clinical trial is expected in the second half of 2022. The trial is an open-label dose escalation trial enrolling up to 40 patients. The current protocol allows for enrollment of up to 40 adult subjects in up to five dose escalation cohorts each, using a standard 3 + 3 dose-escalation design. Before administering the P-BCMA-ALLO1 product candidate, subjects receive a conditioning lymphodepletion chemotherapy regimen. The regimen will be 300 mg/m<sup>2</sup> of cyclophosphamide and 30 mg/m<sup>2</sup> of fludarabine intravenously daily for three consecutive days, followed in two days by a single infusion of P-BCMA-ALLO1.

### P-MUC1C-ALLO1: Allogeneic CAR-T in Multiple Solid Tumor Indications

#### Overview

P-MUC1C-ALLO1 is a fully allogeneic CAR-T product candidate with the potential to treat a wide range of solid tumor indications. The target, MUC1-C, is a tumor selective, aberrantly glycosylated, cleavage product of MUC1, that is highly expressed on most epithelial tumors. We designed P-MUC1C-ALLO1 to leverage the learnings of our P-BCMA-ALLO1 and P-PSMA-101

programs. We received clearance from the FDA on our IND filing and initiated a Phase 1 clinical trial of P-MUC1C-ALLO1 in late 2021.

We used our proprietary piggyBac DNA Delivery System to manufacture a highly purified P-MUC1C-ALLO1 product candidate containing a high percentage of T<sub>SCM</sub> cells that we believe may be the key to developing a CAR-T therapy to treat solid tumors. We use our proprietary Cas-CLOVER platform to genetically engineer T cells in order to reduce or eliminate both GvHD and host versus graft alloreactivity.

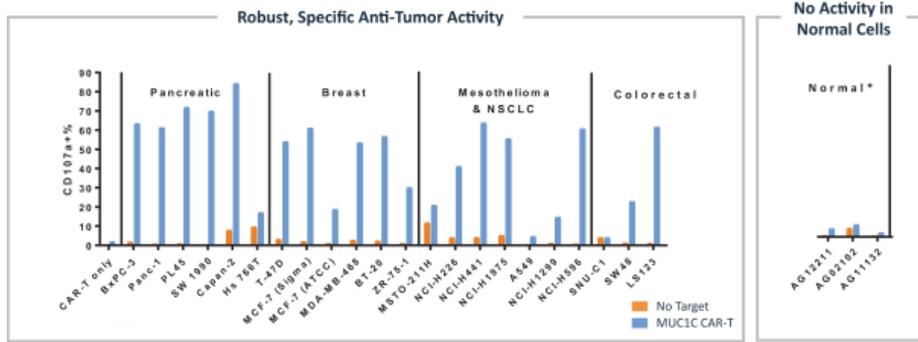
**Target Indication**

We intend to further evaluate and later determine clinical indications for initial development of P-MUC1C-ALLO1 in indications where MUC1-C expression occurs. Approximately 90% of cancers derive from epithelial tissues, and among these cancers a significant percentage express MUC1-C, including common cancers such as breast, colorectal, lung, ovarian, pancreatic and renal cancers.

Tumor Type	MUC1 Expression (%)
Breast	91
Colorectal	81
Esophageal	32
Gastric	77
H&N SCCa	82
Mesothelioma	75
Multiple myeloma	59
Nasopharyngeal	100
NSCLC	99
Ovarian	83
Prostate	79
Pancreatic	81
RCC	84

**Preclinical Data**

In our preclinical studies, an autologous MUC1-C CAR-T showed robust anti-tumor activity against multiple tumor lines:

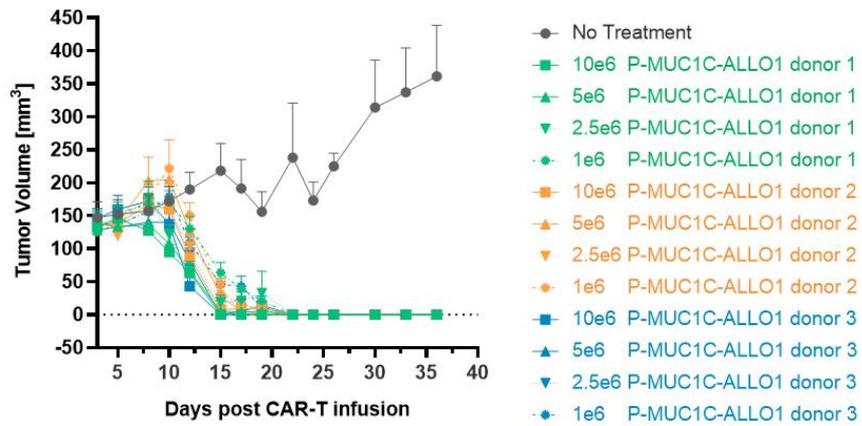


The autologous MUC1-C CAR-T was evaluated for specificity and function using a standard T cell degranulation assay. Degranulation is a surrogate of T cell killing that can be easily measured by FACS staining for intracellular CD107a expression

following co-culture with cells expressing target antigen. mRNA encoding the MUC1-C CAR-T was delivered to pan T cells via electroporation and the cells were rested overnight to allow for translation and surface expression of the CAR. T cells expressing the MUC1-C CAR-T were co-cultured for four to six hours with the indicated tumor cells. Six different cancer types were evaluated in these studies, including both solid and blood tumors. During the co-culture period, CD107a antibody was added to detect degranulation of T cells. The percentage of CD107a T cells is shown in the graph above and indicates tumor-specific activity. Degranulation frequency correlated highly with MUC1C expression on the target tumor cells.

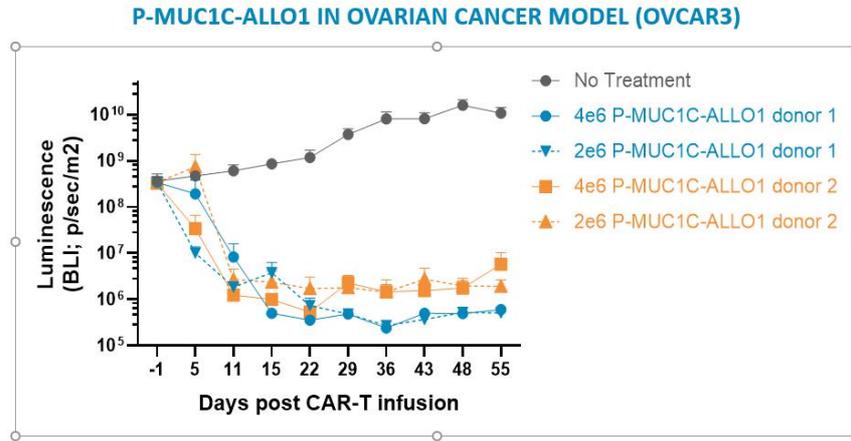
We tested P-MUC1C-ALLO1 in a preclinical xenograft model of triple-negative breast cancer in which immune deficient mice were implanted subcutaneously with a human MDA.MB.468 triple-negative breast cancer cell line. In this model, P-MUC1C-ALLO1 eliminated tumor cells to undetectable levels in both a standard and low dose arm, as shown below:

### P-MUC1C-ALLO1 IN BREAST CANCER MODEL (MDA.MB.468)



We also tested P-MUC1C-ALLO1 in a preclinical xenograft model of ovarian cancer in which immunocompromised (NSG) mice were implanted intraperitoneally with 5 x 10e6 human OVCAR3 ovarian cancer cells 14 days before CAR-T cell injection. In

this model, intraperitoneally administered P-MUC1C-ALLO1 at both a near standard dose ( $4 \times 10^6$ ) and a low stress dose ( $2 \times 10^6$ ) eliminated tumor cells to levels below the limit of detection, as shown in the figure below:



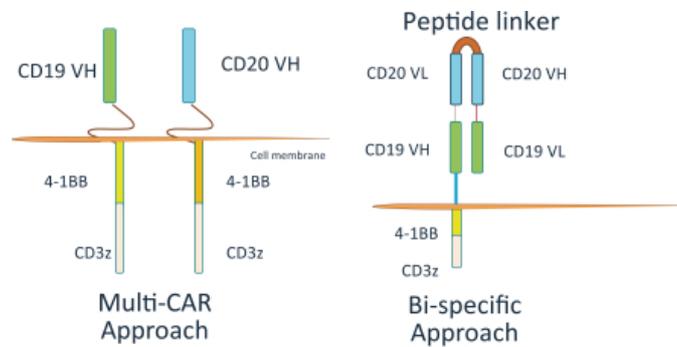
#### Clinical Development Strategy

We received clearance from the FDA on our IND filing in late 2021 and expect initial clinical data from our Phase 1 clinical trial in the second half of 2022. P-MUC1C-ALLO1 was designed to leverage the learnings of our other programs. The current Phase 1 protocol allows for enrollment of up to 100 adult subjects with advance of metastatic epithelial-derived cancers measurable by RECIST and refractory to or ineligible for standard of care therapy. Patients may be enrolled across four arms of single and multiple (cyclic) administrations using two different lymphodepletion regimens of up to five dose escalation cohorts each, using a standard 3 + 3 dose-escalation design. Enrollment will begin in cohorts with a standard 3-day cyclophosphamide and fludarabine lymphodepletion regimen given prior to cell infusion followed by cohorts adding rituximab to the lymphodepletion regimen to reduce the appearance of anti-CAR antibodies and potentially improve persistence. Planned dose escalation in each arm range from  $0.75$  to  $15 \times 10^6$  cells/kg. Treated patients will undergo serial measurements of safety, tolerability, and tumor response and will be followed for up to 15 years after the last dose of P-MUC1C-ALLO1.

The primary objectives for this Phase 1 clinical trial include defining MTD, evaluation of overall safety and tolerability, and preliminary efficacy and disease response. Additional exploratory endpoints will include assessing tumor expression of MUC1-C and correlation to response and expansion kinetics of P-MUC1-ALLO1.

#### Dual CAR-T Allogeneic Program Candidates

The very large cargo capacity of piggyBac allows for the inclusion of much larger or more therapeutic transgenes compared to viral-based technologies. We believe that our ability to include two or more fully functional CAR and/or TCR molecules into a T cell could be a significant competitive advantage. Unlike some competitors that have tried to use a bi-specific or tandem binder to approach this problem, we believe that including two, or more, full CAR or TCR molecules has the potential to be a more effective approach.



## Multi-CAR Approach Enabled by piggyBac

**P-CD19CD20-ALLO1.** P-CD19CD20-ALLO1 is an allogeneic, off-the-shelf CAR-T product candidate in preclinical development for B cell leukemia and lymphoma indications and some autoimmune diseases. P-CD19CD20-ALLO1 contains two fully functional CAR molecules to target cells that express either CD19 or CD20. We believe that by targeting both CD19 and CD20, we have the potential to overcome some of the issues of earlier generation CD19 CAR-T products where antigen escape has been observed. We are developing this product candidate to be fully allogeneic by applying our learnings from the P-BCMA-ALLO1 program. We anticipate an IND filing in 2023.

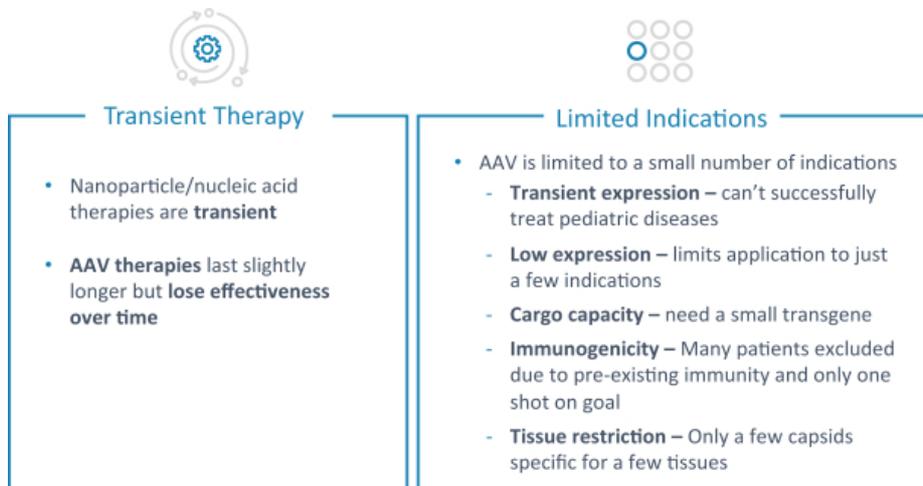
**P-BCMADC19-ALLO1.** P-BCMADC19-ALLO1 is an allogeneic, off-the-shelf CAR-T product candidate in preclinical development for multiple myeloma. P-BCMADC19-ALLO1 contains two fully functional CAR molecules to target cells that express either BCMA or CD19. Based on published studies of CD19 therapeutic candidates in multiple myeloma patients, we believe that targeting both BCMA and CD19 may be more effective than targeting BCMA alone in some patients because it has been hypothesized that there could be myeloma stem cells that express CD19 but do not express BCMA. In addition, including CD19 may prevent anti-drug antibody responses that could shorten the effectiveness of a BCMA-only therapy in some patients. We are developing this product candidate to be fully allogeneic by applying our learnings from the P-BCMA-ALLO1 program. We anticipate an IND filing after analyzing preliminary results observed in the P-BCMA-ALLO1 Phase 1 clinical trial.

**Dual CAR (undisclosed).** Dual CAR (undisclosed) is an allogeneic, off-the-shelf CAR-T product candidate in preclinical development for solid tumors. Dual CAR (undisclosed) contains two fully functional CAR molecules to target cells that express either of two targets that are currently undisclosed. We are developing this product candidate to be fully allogeneic by applying our learnings from the P-MUC1C-ALLO1 program. We anticipate an IND filing after analyzing preliminary results observed in the P-MUC1C-ALLO1 Phase 1 clinical trial.

### Liver Directed Gene Therapy

The concept of *in vivo* gene therapy arose during the early 1970's, with initial human testing beginning in 1980. However, early clinical failures held back the development of the field and associated funding and progress was slow until the last decade. Within the last decade, gene therapy has expanded and gained more acceptance. Due to some clinical successes and associated funding and merger and acquisition activity, the field is now emerging as a major focus of new therapeutic development. Despite this re-emergence of interest and development, much of the *in vivo* gene therapy work faces significant challenges.

Among the primary limitations of most current gene therapies are the fact that these therapies are generally transient in nature and, therefore, limited to a narrow range of indications. These limitations are driven by a number of factors associated with using AAV as the standard method of delivering the therapeutic transgene. First, specific AAV capsids can be used to effectively infect a number of cell types *in vivo*, but AAV does not generally integrate into the genome without the virus' rep gene, which is removed in gene therapy applications to accommodate the therapeutic transgene. The lack of integration results in low expression levels of the therapeutic transgene that generally decrease over time. As cells divide, expression is eventually lost, thus making it difficult or impossible to use AAV-mediated gene therapies in rapidly dividing tissues, such as the pediatric liver. Unfortunately, the pediatric liver is the tissue that needs to be targeted in order to treat many monogenetic inborn errors of metabolism, particularly in the majority of patients that are more severely affected. Second, AAV has a relatively small cargo capacity, which can limit its ability to treat indications where a larger therapeutic transgene is needed to correct the underlying disease. The relatively small cargo capacity also limits the inclusion of additional features, such as larger tissue-specific promoters, insulators or safety switches. Third, AAV itself can be immunogenic with pre-existing antibodies in some patients. Furthermore, AAV-based therapies often elicit antibody-based immune reactions, making repeat dosing very challenging. Finally, earlier-generation AAV therapies require relatively high doses of virus to deliver enough of the gene to have a clinical effect, which creates safety issues associated with the AAV itself.



Our technology is designed to address the shortcomings of other AAV approaches in several important ways. First, by combining our piggyBac technology with AAV, we believe we can create a therapeutic that integrates the therapeutic transgene into the DNA and becomes a stable part of the patient's DNA, even in rapidly dividing cells. This results in the potential for single-treatment cures, even when treating indications that manifest predominantly in the pediatric liver. Second, piggyBac is highly efficient at integrating into DNA, resulting in stable and high expression levels of therapeutic transgenes even at relatively low doses, which we believe may allow potent activity in indications that are not currently treatable with AAV-only technologies. Furthermore, piggyBac in combination with AAV might be effective at much lower viral doses when compared with AAV-only technologies and would therefore mitigate some of the risk of toxicity due to AAV itself.

We are also combining our piggyBac technology with our nanoparticle technology to deliver therapeutic transgenes in an effort to eliminate the need for AAV altogether. This would completely avoid virus-related toxicity and also enable delivery of larger genes and repeat dosing, which would further expand the number of indications that could be treated.

While our technology platforms enable the development of *in vivo* gene therapies in a wide array of applications, we are focusing our initial efforts on liver-directed gene therapy, where we have promising preclinical data and believe we have a significant competitive advantage over early generation gene therapies. We believe that our technology has the potential to address indications and patient populations that AAV-only technologies will not be able to address. In some cases, we believe that by combining our



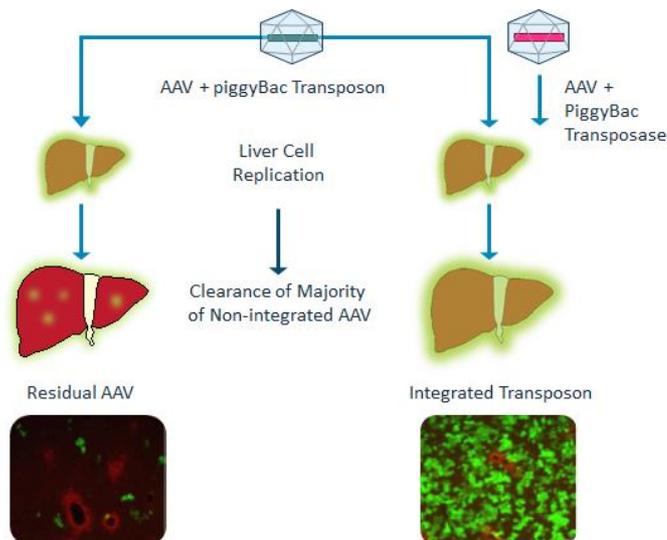
### Single Treatment Cures

- **piggyBac permanently and stably integrates into DNA** resulting in the potential for **long-term stable expression**
- **piggyBac** has the potential to **work in juvenile liver** without diluted expression over time

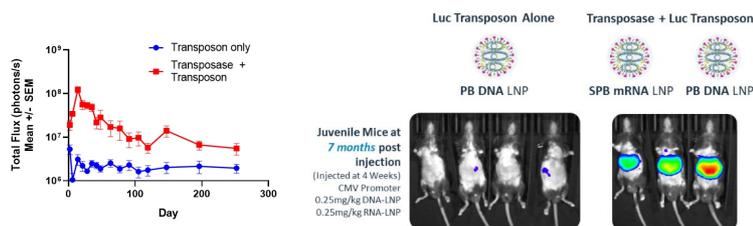
### Countless Indications

- piggyBac has the potential to overcome the limitations of other systems
  - **High activity in virtually any cell type** enabling broad applicability
  - Results in **normal (wild type or higher) protein expression levels**
  - **Very large cargo capacity**
  - **No to low immunogenicity observed**
  - Ability to deliver piggyBac to many different cells and tissues both *ex vivo* and *in vivo*

Any AAV-based system can be converted into a piggyBac-AAV vector by simply adding the piggyBac ITRs, which can be as small as 50 base pairs each, inside of the AAV ITRs (AAV + piggyBac transposon). We expect this vector will perform the same as a standard AAV vector in the absence of the piggyBac transposase, which can be delivered in a second AAV (AAV + piggyBac transposase). When using an enhanced green fluorescent protein (EGFP) reporter gene as a surrogate for a therapeutic transgene and injecting the AAV + piggyBac transposon (no transposase) into animals, we observed a low level of EGFP expression in the liver of the mouse (lower left panel). Similar to other standard AAV therapies, there was a low expression level due to episomal (non-integrated) AAV and as such, it diminished over time, especially as the cells divided. However, when the AAV + piggyBac transposase was co-injected with the AAV + transposon, we observed a high, stable level of expression in a majority of hepatocytes, as shown in the lower right panel. In this case, the piggyBac transposase pulled the transgene out of the transposon and stably integrated it into the genome. As the cells divided, they replicated the integrated therapeutic transgene so all progeny cells permanently expressed it. This strategy has been used in three separate mouse models of various severe congenital liver genetic diseases: OTC deficiency, citrullinemia Type I and progressive familial intrahepatic cholestasis Type III, demonstrating the potential for single-treatment cures in each case.



One of the goals for our gene therapy programs is to be able to deliver our gene engineering technologies by nanoparticle to eliminate the need to use AAV due to its limitations. In preclinical work, we are seeing positive results in delivering piggyBac transposon (DNA) and piggyBac transposase (RNA) into animal models, resulting in significant integration and transgene expression in all zones of the liver. The following figure represents an experiment where we co-administered piggyBac transposon (DNA) and piggyBac transposase (RNA) formulated into separate nanoparticles to a juvenile mouse and measured levels of expression of a reporter gene in the liver out to 7 months. These data, while preliminary, potentially represent a significant step forward toward our goal of nanoparticle delivery of piggyBac, which we believe would represent a significant advance compared to traditional gene therapy.



## Our Gene Therapy Programs

### P-OTC-101

#### Overview

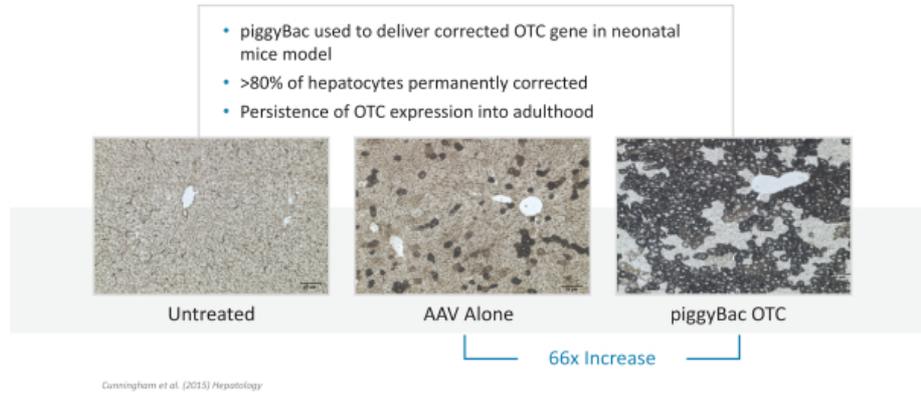
P-OTC-101 is an *in vivo* liver-directed gene therapy candidate for the treatment of OTC deficiency, which we believe has the potential to achieve single-treatment, lifetime durable responses. We are evaluating our proprietary piggyBac DNA Delivery System combined with a liver-directed AAV or nanoparticles for the *in vivo* treatment of OTC deficiency. OTC deficiency is an often fatal or morbid urea cycle disease caused by congenital mutations in the OTC gene with a high unmet medical need.

#### Target Indication

OTC is a rare genetic disorder characterized by complete or partial lack of the enzyme OTC. OTC is an enzyme that plays a role in the breakdown and removal of nitrogen from the body, a process known as the urea cycle. The lack of the OTC enzyme results in excessive accumulation of nitrogen in the form of ammonia (hyperammonemia) in the blood. Excess ammonia, which is a neurotoxin, travels to the central nervous system through the blood, resulting in symptoms of lethargy, vomiting, irritability and, in more severe cases, decreased muscle tone, seizures, enlarged liver, respiratory difficulties and death. A severe form of the disorder affects some infants, typically newly born males. A milder form of the disorder affects some children later in infancy. More severe forms of OTC comprise a high unmet medical need.

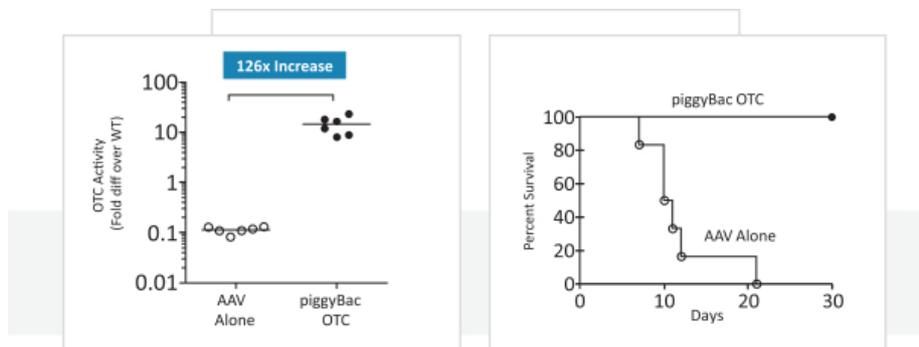
#### Preclinical Data

In preclinical studies conducted by our academic collaborators, the approach of combining piggyBac with AAV (piggyBac OTC) demonstrated stable and high level expression of a therapeutic transgene in the mouse liver compared to AAV-only technologies.



In the same study, treatment with piggyBac OTC resulted in a 126-fold increase in OTC levels compared with AAV alone and survival of all the animals in the treated group versus 0% survival in the AAV alone group. The expression of OTC at more than 10 times the normal (WT) levels also highlights the potential to lower the dose of piggyBac-OTC compared with standard AAV-alone

therapies and the ability to still achieve single-treatment, durable responses, which would have additional cost and tolerability benefits compared to standard AAV therapies.



## P-FVIII-101

### Overview

P-FVIII-101 is a liver-directed gene therapy combining piggyBac technology with our nanoparticle delivery technology for the *in vivo* treatment of Hemophilia A.

We are using our proprietary piggyBac DNA Delivery System combined with our proprietary nanoparticle technology to deliver a Factor VIII therapeutic transgene. This program is included in the Takeda Collaboration Agreement, and therefore Takeda is obligated to fund the program and will determine the timeline to IND submission.

### Target Indication

Hemophilia A is a bleeding disorder caused by a deficiency in Factor VIII production with a high unmet need. Disease can range in severity from mild to severe and Factor VIII levels are correlated with the severity of the disease.

### Preclinical Data

Our preclinical data demonstrates an ability to correct Factor VIII deficiency to normal levels in a juvenile mouse model using nanoparticle delivery of our P-FVIII-101 potential product candidate.

### Takeda Collaboration

In October 2021, we entered into the Takeda Collaboration Agreement pursuant to which we granted to Takeda a worldwide exclusive license under our piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms to research, develop, manufacture and commercialize gene therapy products for certain indications, including Hemophilia A. We will collaborate with Takeda to initially develop up to six *in vivo* gene therapy programs and Takeda also has an option to add two additional programs to the collaboration. We are obligated to lead research activities up to candidate selection, after which Takeda is obligated to assume responsibility for further development, manufacturing and commercialization of each program.

Under the Takeda Collaboration Agreement, Takeda made an upfront payment to us of \$45.0 million. Takeda is also obligated to provide funding for all collaboration program development costs including our P-FVIII-101 program; provided that we are obligated to perform certain platform development activities at our own cost. Timelines for P-FVIII-101 and other programs subject to the Takeda Collaboration Agreement will be driven by Takeda.

### Potential Additional Programs and Partnership Opportunities

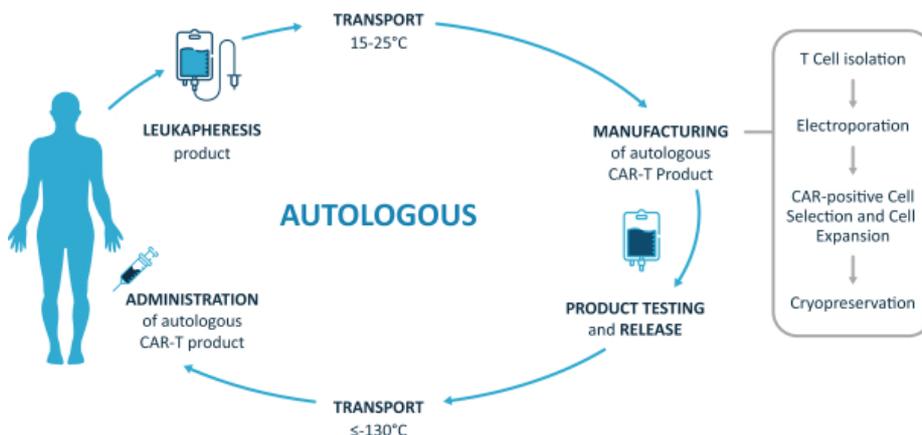
While we have leveraged our platform technologies to currently pursue the development of CAR-T and liver-directed gene therapy product candidates, our technologies have broad applicability across a wide array of cell and gene therapeutic modalities and

diseases. Beyond the current pipeline, we and our collaborators have preclinical data that illustrate future potential applications of the technology platforms when combined in various ways. We may in the future use these tools to create T cell-based products to address indications beyond oncology, such as autoimmune diseases, infectious diseases, allergy-related diseases or even neurodegenerative diseases. CAR-T may also be used as an alternative and non-myeloablative preconditioning regimen for stem cell transplants. Our technologies also work well in other cell types and tissues including induced pluripotent stem cells, natural killer cells, HSCs, B cells, hepatocytes, muscles and many others, which could enable additional approaches for future therapeutics in a variety of indications. Lastly, we could use our Cas-CLOVER technology directly *in vivo*, similar to the approaches taken by other gene editing companies.

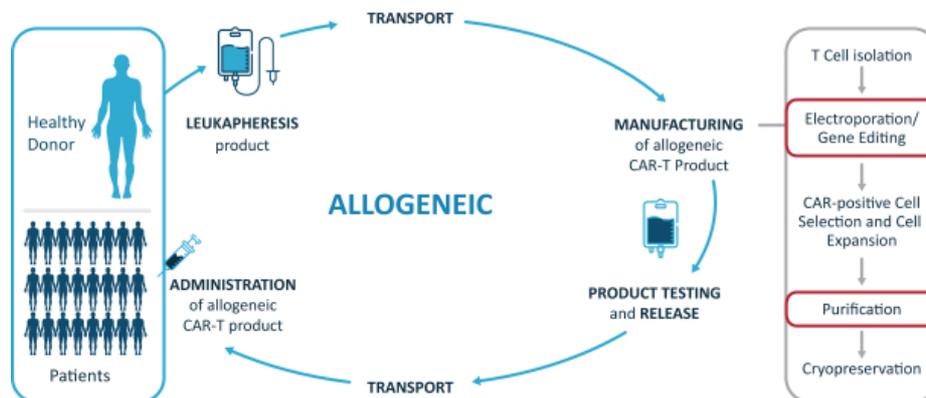
### Our CAR-T Manufacturing Processes

Our autologous CAR-T product candidates consist of patient T cells that have been genetically engineered to express a CAR molecule and other genes. PBMCs are harvested by a standard leukapheresis procedure at the enrolling hospital, with the leukapheresis cells transported to the manufacturing site immediately subsequent to the procedure.

Manufacturing of autologous CAR-T product candidates includes CD4-positive and CD8-positive T cell isolation via positive selection, electroporation of the piggyBac DNA transposon transgene (encoding the CAR molecule gene, the DHFR positive selection gene and the safety switch gene) and Super piggyBac transposase RNA (the enzyme that mobilizes the piggyBac transposon transgene), CAR-positive T cell selection via methotrexate, and cell expansion. The final product is then bagged and cryopreserved. Following product release for administration, cryopreserved product candidates are shipped by courier to the pharmacy or applicable cell therapy facility of the enrolling study center where they are stored until the time of administration.



The manufacturing process for our allogeneic product candidates is nearly identical to the process for our autologous product candidates, except for the gene editing, a related additional purification step and the addition of booster molecules:



### CAR-T Contract Manufacturing

We work with a number of third-party contract manufacturers for production of our product candidates. For the manufacturing of P-PSMA-101 Phase 1 clinical trial, we are utilizing C3i, a contract manufacturer in Montreal, Quebec affiliated with the University of Montreal Hospital. For the manufacturing of P-BCMA-ALLO1 we have a relationship with WuXi AppTec, Inc., from which we receive clinical supplies and on which we may rely on for commercial manufacturing. We have also initiated tech transfer to potentially allow manufacturing of P-BCMA-ALLO1 in our pilot plant. For our other product candidates, we are evaluating various third-party manufacturers for clinical supply. We also work with a variety of suppliers to provide our manufacturing raw materials and we currently source our media from Stemcell and DNA components from Aldevron. We believe that our relationships with our contract manufacturers and suppliers are good.

We also have an internal pilot GMP manufacturing facility in San Diego adjacent to our headquarters to develop and manufacture preclinical materials and clinical supplies for Phase 1 and Phase 2 clinical trials. We commenced operations in this facility in the second half of 2020. We began GMP manufacturing in Q3 2021 and are using the pilot facility initially for manufacturing our P-MUC1C-ALLO1 program. In the future, we may also build one or more commercial manufacturing facilities for any approved product candidates.

### Commercialization Plans

We possess global rights to our product candidates and discovery programs. We intend to retain significant development and commercialization rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing, or commercial product distribution capabilities and have no experience as a company in marketing products. We plan to build the necessary infrastructure and capabilities over time in the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

### Competition

The biotechnology industry, and specifically the CAR-T and gene therapy sciences, are characterized by intense and rapidly changing competition to develop new technologies and proprietary products. While we believe that our proprietary approach and scientific expertise in CAR-T and gene therapies provide us with competitive advantages, we face potential competition from many different sources, including larger and better-funded pharmaceutical companies, as well as academic and research institutions. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient, or cost less than any products that we may develop. The key competitive factors affecting the success of our programs are likely to be their efficacy, safety, convenience and cost.

There are other organizations currently working toward commercializing existing therapies and/or new therapies for our initially selected indications. If these efforts are successful and their product candidates are approved or marketed prior to ours, it is possible they may increase the barriers to adoption of our product candidates.

Due to the promising clinical therapeutic effect of CAR-T product candidates in clinical trials, we anticipate direct competition from other organizations developing advanced T cell therapies and other types of oncology therapies. This would include companies in the CAR-T space including: Adaptimmune Therapeutics plc, Allogene, Inc., Astellas Pharma, Inc., Autolus Ltd., Bellicum Pharmaceuticals Inc., Bluebird Bio, Inc., Collectis S.A., Janssen Pharmaceuticals Inc., Juno Therapeutics, Inc. (acquired by Celgene Corporation, now a Bristol-Myers Squibb Company), Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Legend Biotech Corporation, Novartis AG and Takeda.

Immunotherapy and gene therapy approaches are further being pursued by several smaller biotechnology companies as well as larger pharmaceutical companies. We also face competition from non-cell-based treatments offered by companies such as Amgen Inc., AstraZeneca plc, Bristol-Myers Squibb Company, F. Hoffman-La Roche AG, GlaxoSmithKline plc, Merck & Co., Inc. and Pfizer Inc. Many of our competitors, either alone or with their collaboration partners, have substantially greater financial, technical and other resources, such as larger research and development staff and/or greater expertise in research and development, manufacturing, preclinical testing and conducting clinical trials.

Recent approvals and M&A activity have also spurred the creation of many companies now pursuing gene therapy technologies and indications. The landscape is evolving rapidly and these companies are too numerous to list, but would include companies such as Alnylam Pharmaceuticals, Inc., Astellas, Beam Therapeutics, Inc., BioMarin Pharmaceuticals, Inc., Bluebird Bio, Collectis, CRISPR Therapeutics, AG, Editas Medicines, Inc., F. Hoffman-La Roche AG (acquired Spark Therapeutics, Inc.), Generation Bio, Inc., Intellia Therapeutics, Inc., LogicBio Therapeutics, Inc, Moderna, Inc., Novartis AG (acquired AveXis, Inc.), Passage Bio, Inc., Sangamo Therapeutics, Inc., Sarepta Therapeutics, Inc. and Ultragenyx, Inc.

In addition, smaller or early-stage companies may compete with us through collaborative arrangements with more established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these enterprises. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries are prevalent and may result in even more resources being concentrated among a smaller number of our competitors. Our competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials.

## **Intellectual Property**

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired or licensed from third parties. We will also seek to rely on regulatory protection afforded through orphan drug designations, inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

Our intellectual property estate is designed to provide multiple layers of protection, including: (1) patent rights with claims directed to platform technologies; (2) patent rights with claims directed to core components used in our products; (3) patent rights covering specific products; (4) patent rights covering methods of treatment for therapeutic indications; (5) patent rights covering methods of use for core components and platform technologies; and (6) patent rights covering innovative manufacturing processes. We also rely on trade secrets that may be important to the development of our business.

We believe our current layered patent estate, together with our efforts to develop and patent next generation technologies, provides us with substantial intellectual property protection.

We have filed or will file for patent protection in the United States and internationally for P-PSMA-101, P-BCMA-ALLO1, P-MUC1C-ALLO1, our Dual CAR product candidates, P-PSMA-ALLO1 and P-OTC-101 and P-FVIII-101, our gene therapy product candidates. However, the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties.

With respect to the platform technologies and core components described above (e.g., T<sub>SCM</sub> compositions and manufacturing method, genetically-modified HSC manufacturing method, inducible safety switch, piggyBac DNA Delivery System, Cas-CLOVER gene editing technology, booster molecules for enhanced immune cell expansion, armoring strategies, and nanoparticle delivery methods) the intellectual property estate is comprised predominantly of company-owned or company-acquired intellectual property. We expect to file additional patent applications in support of current and new product candidates as well as new platform and core technologies. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection

of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent or delays on the part of a patentee. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the 152 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that maximum coverage and value are obtained for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or product candidates.

#### ***Company-Owned Intellectual Property***

P-PSMA-101 is covered by a number of filings, including, a published PCT application filed in March 2019 that entered the national stage in September of 2020. National phase applications are pending in several countries outside the United States, including most major market countries. Composition of matter claims issuing from this application would not expire before 2039.

P-BCMA-ALLO1 is covered by a number of filings, including, a published PCT application filed in December 2018 that entered the national stage in June of 2020. National phase applications are pending in several countries outside the United States, including most major market countries. Composition of matter claims issuing from this application would not expire before 2038.

P-MUC1C-ALLO1 is covered by a number of filings, including a published PCT application filed in 2017 that entered the national phase in January of 2019. National phase applications are pending in several countries outside the United States, including most major market countries. Composition of matter claims issuing from this application would not expire before 2037. In addition, an unpublished PCT application filed in September of 2020 will publish in March 2021. Composition of matter claims issuing from these applications would not expire before 2040.

Our gene therapy programs including P-OTC-101 and P-FVIII-101 are covered by a number of filings, including as of March 4, 2020, a pending provisional application that is due for conversion to a non-provisional application in March 2021. Composition of matter claims issuing from this application would not expire before 2041.

Our P-PSMA-ALLO1 and Dual CAR Programs, including P-CD19CD20-ALLO1, P-BCMACD19-ALLO1 and Dual CAR (Undisclosed), are earlier in development and our intellectual property coverage is still being developed.

Core components of each of these product candidates are protected by company-owned platform applications directed to Centyrin binders (P-PSMA-101) or heavy-chain-only antibody fragment binders (P-BCMA-ALLO1), booster molecules for enhanced immune cell expansion (currently all allogeneic products), early memory T-cells (including T<sub>SCM</sub>) and methods of producing same (P-PSMA-101, P-BCMA-ALLO1 and P-MUC1C-ALLO1), piggyBac transposition systems (all products), inducible safety switches (all products), marker genes for facilitating simultaneous selection and expansion of modified cells for product manufacture, and self-cleaving peptides for trivalent transposon constructs (all products). Notably in December 2019, we were issued a U.S. patent that has claims that cover any modified T cell product that has 25% or more T<sub>SCM</sub> cells and has a patent term expiring in 2037. We also have issued U.S. patents covering manufacturing methods and cell culture media used to produce these genetically modified T<sub>SCM</sub> cells that have patent terms expiring in 2037. We also have an issued composition of matter patent in the U.S. protecting our Cas-CLOVER site-specific gene editing system that has a patent term expiring in 2032. We also have issued composition of matter patents in the U.S. protecting our piggyBac DNA Delivery System that have patent terms expiring in 2030.

### **Acquired Intellectual Property**

As a spin-out from Transposagen Biopharmaceuticals, Inc., or Transposagen, at inception, we acquired intellectual property related to piggyBac transposition systems and methods for use. This acquisition further comprised intellectual property related to next-generation gene editing systems and methods for use.

We acquired Vindico NanoBioTechnology, LLC (formerly known as Vindico NanoBioTechnology, Inc.) in October 2016. As part of this transaction, we acquired intellectual property related to polymer-based nanoparticle compositions and methods of use for delivery of, for example, gene therapy technologies.

### **Collaborations**

On October 11, 2021, we entered into the Takeda Collaboration Agreement with Takeda pursuant to which we granted to Takeda a worldwide exclusive license under the Company's piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms to research, develop, manufacture and commercialize gene therapy products for certain indications, including Hemophilia A. The parties will collaborate to initially develop up to six *in vivo* gene therapy programs and Takeda also has an option to add two additional programs to the collaboration. We are obligated to lead research activities up to candidate selection, after which Takeda is obligated to assume responsibility for further development and commercialization of each program.

Under the Takeda Collaboration Agreement, we received an upfront payment from Takeda of \$45.0 million. Takeda is also obligated to provide funding for all collaboration program development costs; provided that we are obligated to perform certain platform development activities at its own cost. Under the Takeda Collaboration Agreement, we are eligible to receive preclinical milestone payments that could potentially exceed \$82.5 million in the aggregate if preclinical milestones for all six programs are achieved. We are also eligible to receive future clinical development, regulatory and commercial milestone payments of \$435.0 million in the aggregate per target, with a total potential deal value over the course of the collaboration of up to \$2.7 billion, if milestones for all six programs are achieved and up to \$3.6 billion if the milestones related to the two optional programs are also achieved. We are entitled to receive tiered royalty payments on net sales in the mid-single to low double digits, subject to certain standard reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the latest of the expiration of the licensed patents covering such product in such country, ten years from first commercial sale of such product in such country, or expiration of regulatory exclusivity for such product in such country.

Either party may terminate the Takeda Collaboration Agreement in the event of an uncured material breach of the other party, in the case of insolvency of the other party or in the event the other party makes certain challenges to the patents of such party. Takeda may terminate the Takeda Collaboration Agreement for convenience upon prior written notice or in the event of a safety concern immediately upon written notice.

### **In-License Agreements**

#### *License Agreement with Janssen Biotech*

On August 3, 2015, we entered into a license agreement, or the Janssen Agreement, with Janssen Biotech Inc., or Janssen, pursuant to which we obtained an exclusive, sublicensable, worldwide license to research, develop, manufacture and commercialize pharmaceutical products comprising autologous CAR-modified T-cells or any CAR-modified natural killer or CAR-modified natural-killer-like cells expressing certain Centyrin molecules, for the treatment or prevention of any disease in humans. We are obligated to

use commercially reasonable efforts to develop and commercialize at least one such licensed product. We utilize these license rights in our P-BCMA-101 and P-PSMA-101 product candidates. Under the Janssen Agreement, we also have the right to engage with authorized third parties to screen Janssen's Centyrin library for agents that bind or modify targets of interest for our internal research and development purposes for potential use in a licensed product.

Pursuant to the Janssen Agreement, we paid Janssen an upfront fee of \$0.2 million. As of December 31, 2021, we have paid approximately \$3.3 million in milestone development fees relating to P-BCMA-101 and approximately \$0.7 million in milestone development fees relating to P-PSMA-101. We are required to pay Janssen up to an aggregate of \$75.8 million upon the achievement of certain clinical, regulatory and sales milestones for the first licensed product and up to an aggregate of \$46.8 million upon the achievement of certain clinical, regulatory and sales milestones for each licensed product thereafter. We are also obligated to pay, on a product-by-product and country-by-country basis, tiered royalties in the low single-digit percentage range on annual net sales, with the royalty rates varying depending on if there is a valid claim present within the licensed patent rights covering the licensed product in the applicable country in which the net sales occur. The royalty rates are also subject to reduction upon certain other events.

The Janssen Agreement will terminate on the last to expire royalty term, which is determined on a licensed product-by-licensed product and country-by-country basis, and is the later of (1) 10 years from the first commercial sale of the licensed product in the country, (2) the last to expire valid claim within the licensed patent in the country or (3) expiry of regulatory exclusivity granted by the prevailing governmental authority for the licensed product in the country. We also have the right to terminate the Janssen Agreement in its entirety or on a licensed product-by-licensed product basis, for any reason upon 60 days prior written notice to Janssen. Either party may terminate the Janssen Agreement upon a material breach by the other party that is not cured within 60 days after receiving written notice, or upon giving written notice within 30 days of the other party's bankruptcy. If we terminate the Janssen Agreement for convenience or Janssen terminates the Janssen Agreement due to our breach of our diligence obligations thereunder, Janssen will have an option to negotiate a license from us to research, develop and commercialize the Centyrin CAR molecules and/or Centyrin therapeutic molecules. If Janssen exercised this option, Janssen would be obligated to pay us a fee in the low six figure dollar range.

#### *April 2017 Commercial License Agreement with TeneoBio*

On April 27, 2017, we entered into a commercial license agreement, or the 2017 TeneoBio Agreement, with TeneoBio, Inc., or TeneoBio, pursuant to which we obtained an exclusive, sublicenseable, worldwide license to use and develop pharmaceutical products comprising allogeneic T-cells expressing a CAR molecule containing certain heavy-chain-only sequences provided by TeneoBio (a CAR containing a non-naturally occurring heavy-chain-only antibody fragment) for the treatment of human disease. We utilize these license rights in our P-BCMA-ALLO1 product candidate.

Pursuant to the 2017 TeneoBio Agreement, we have paid TeneoBio \$0.5 million through our selection of the antibodies licensed under the 2017 TeneoBio Agreement. We are required to pay TeneoBio up to an aggregate of \$20.5 million upon the first achievement of certain clinical and regulatory milestones for any allogeneic product and up to an aggregate of \$20.5 million upon the first achievement of certain clinical and regulatory milestones for any autologous product. We are also obligated to pay, on a product-by-product and country-by-country basis, a royalty in the low single-digit percentage on net sales of all licensed products.

The 2017 TeneoBio Agreement will terminate on the last to expire valid claim of the licensed patents in all countries. We may also terminate the 2017 TeneoBio Agreement at any time upon 60 days prior written notice to TeneoBio. Either party may terminate the 2017 TeneoBio Agreement upon a material breach by the other party that is not cured within 90 days after receiving written notice of the breach, or upon a bankruptcy of the other party.

#### *August 2018 Commercial License Agreement with TeneoBio*

On August 3, 2018, we entered into a commercial license agreement, or the 2018 TeneoBio Agreement, with TeneoBio for the development and use of TeneoBio's human heavy-chain-only antibodies in CAR-T cell therapies. Under the terms of the 2018 TeneoBio Agreement, we have the option to obtain exclusive rights to research, develop and commercialize up to a certain number of targets from TeneoBio.

Pursuant to the 2018 TeneoBio Agreement, we paid TeneoBio an upfront fee of \$4.0 million. We are required to pay additional fees in the low to mid six figure dollar range upon (1) selecting exclusivity for a particular target, which restricts TeneoBio from licensing that particular target to a third party for a period of time, (2) continuing exclusivity for any selected target on each anniversary thereafter and (3) exercising our commercial option for each target. We are required to pay TeneoBio up to an aggregate of \$31.0 million upon the first achievement of certain clinical and regulatory milestones for each product. We are also obligated to pay, on a product-by-product and country-by-country basis, a low single-digit percentage royalty on net sales of any licensed products. The royalty rate is subject to reduction upon certain events.

The 2018 TeneoBio Agreement will terminate on the last to expire valid claim of the licensed patents in all countries. We may also terminate the 2018 TeneoBio Agreement with respect to one or more targets at any time upon 60 days prior written notice. Either party may terminate the 2018 TeneoBio Agreement upon a material breach by the other party that is not cured within 90 days after receiving written notice of the breach, or upon a bankruptcy of the other party.

#### *License Agreement with Genus Oncology*

On October 24, 2019, we entered into a license agreement, or the Genus Agreement, with Genus Oncology, LLC, or Genus. Pursuant to the Genus Agreement, we paid Genus an upfront fee of \$1.5 million and Genus granted us the option, which was exercised for an additional \$1.5 million in April 2020, to obtain an exclusive, sublicenseable, worldwide license under certain patents and a non-exclusive, sublicenseable, worldwide license under certain know-how controlled by Genus to research, develop and commercialize pharmaceutical products incorporating CAR cells expressing antibodies and derivatives thereof targeting MUC1, or a Genus licensed product, and a non-exclusive, sublicenseable, worldwide license under certain patents and know-how controlled by Genus to research, develop and commercialize companion diagnostics for the treatment, prevention and palliation of human diseases and conditions. The licenses granted pursuant to the Genus Agreement are subject to certain rights retained by an upstream licensor and the rights of the U.S. government. The retained rights of the upstream licensor pertain only to the ability of the upstream licensor to conduct teaching, education and other non-commercial research activities in the licensed field and for other academic, governmental or not-for-profit organizations to conduct non-commercial research activities in the licensed field, and do not limit our ability to pursue our programs and product candidates. We use a Genus antibody or derivative thereof targeting MUC1 as a binder in our P-MUC1C-ALLO1 product candidate. Multiple other aspects of our P-MUC1C-ALLO1 product candidate are covered by other patents and intellectual property that we own or license and are not subject to rights of the U.S. government.

Pursuant to the Genus Agreement, we are also required to pay Genus up to an aggregate of \$71.0 million upon first achievement of certain clinical, regulatory and sales milestones for any Genus licensed product and companion diagnostics. We are also obligated to pay, on a product-by-product and country-by-country basis, tiered royalties in the low to mid-single-digit percentage on net sales of any Genus licensed products and related companion diagnostics, subject to certain customary reductions.

The Genus Agreement will expire on the last to expire royalty term, which is determined on a product-by-product and country-by-country basis, and is the later of (1) the last to expire valid claim within the licensed patents covering the Genus licensed product in the country, (2) expiration of regulatory exclusivity for the Genus licensed product in the country and (3) 10 years from the first commercial sale of the Genus licensed product in the country. We may also terminate the Genus Agreement at any time upon 30 days prior written notice to Genus. Either party may terminate the Genus license agreement upon a material breach by the other party that is not cured within 90 days after receiving written notice of the breach. Genus also has the right to terminate the Genus Agreement immediately upon our bankruptcy or if we fail to initiate a Phase 1 clinical trial for a Genus licensed product within 20 months after approval of an IND submitted for such Genus licensed product.

#### *Amended and Restated License Agreement with HMGU*

On March 12, 2021, we entered into an amended and restated patent license agreement, or the HMGU License Agreement, with Helmholtz-Zentrum München—Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH, or HMGU, pursuant to which we obtained exclusive worldwide rights to research, develop, manufacture and commercialize products and services claimed by certain patent applications and patents owned by HMGU covering the nuclease Clo051 in certain fields of use, including human pharmaceutical products. We utilize these license rights in our Cas-CLOVER gene editing technology including P-BCMA-ALLO1, P-MUC1C-ALLO1 and our other planned allogeneic programs.

Pursuant to the HMGU License Agreement, we paid HMGU an upfront fee of \$11,506, equal to €10,000 on the date of payment. We are required to pay HMGU annual maintenance fees credited against royalties due for the same year. We are also required to pay HMGU up to an aggregate of €1.7 million upon the first achievement of certain clinical and regulatory milestones for the first licensed product where Clo051 is part of the therapeutic agent and up to an aggregate of €0.9 million upon the first of certain clinical and regulatory milestones for the first licensed product where Clo051 is not part of the therapeutic agent. We are obligated to pay, on a licensed product-by-licensed product or licensed service-by-licensed service and country-by-country basis, royalties in the low single-digit percentage range on annual net sales, with the royalty rates varying depending on whether the licensed products are therapeutics or the licensed services are for therapeutic use and whether Clo051 is part of the therapeutic agent or used to generate the therapeutic agent. We currently use Clo051 as part of our gene engineering technology to generate our product candidates.

The HMGU License Agreement will terminate on the last to expire royalty term, which is determined on a licensed product-by-licensed product and country-by-country basis. We also have the right to terminate the HMGU License Agreement upon giving written notice within 3 months prior to the end of a calendar year. Either party may terminate the HMGU License Agreement upon a material breach by the other party that is not cured within six weeks after receiving written notice of the breach. The HMGU License Agreement terminates automatically if we become bankrupt.

## **Government Regulation**

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

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

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each treatment site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

## ***Preclinical and Clinical Development***

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level as set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to 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 investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol

amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### ***BLA Submission and Review***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies, and the sponsor of an approved BLA is also subject to an annual program fee.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP 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 treatment sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

### ***Expedited Development and Review Programs***

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products 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 and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the 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 BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product 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 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, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product 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 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 compared to marketed products. For products containing new molecular entities, 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 (compared with ten months under standard review).

Additionally, products 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 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. 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, 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 is intended to fulfill the 21st Century Cures Act requirement that FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it 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; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products 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 sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

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.

#### ***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 a 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 BLA, to market the same 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. Orphan drug exclusivity does not prevent 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 BLA application 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.

#### ***Post-Approval Requirements***

Any products manufactured or distributed by us pursuant to FDA approvals 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 user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. 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 upon us and our third-party manufacturers. 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 upon us and any third-party manufacturers that we may decide to use. 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 Reference Product Exclusivity***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. 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, can be 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. 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, recent 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.

#### ***Other U.S. Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS (such as the Office of Inspector General and the Health Resources and Service Administration), the Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers and purchasers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices, including our arrangements with physicians, may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law 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 federal False Claims Act, or FCA.

The federal false claims and civil monetary penalty laws, including the FCA, which can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal healthcare programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain healthcare providers, healthcare clearinghouses, and health plans, known as covered entities, and independent contractors, or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates, as well as their covered subcontractors. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

#### ***Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Coverage and adequate reimbursement from governmental healthcare

programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance. Similarly, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products.

Third-party payors decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

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

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, we cannot be sure that the level of reimbursement will be adequate. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Additionally, in the United States there is no uniform policy among third-party payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Certain of our products, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs or biologicals, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### **Healthcare Reform**

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer
- price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% starting on January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' 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 additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the FCA and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- 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;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a licensure framework for follow on biologic products.

There have been legal and political challenges to certain aspects of the ACA. President Trump signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, the Tax Cuts and Jobs Act of 2017 was enacted which repeals, effective January 1, 2019, the tax penalty for an individual's failure to maintain ACA-mandated health insurance, commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, the BBA, and the CARES Act will stay in effect through 2031 unless additional Congressional action is taken. These reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The expansion of new programs such as Medicare payment for performance initiatives for physicians, also referred to as the Quality Payment Program, under the Medicare Access and CHIP Reauthorization Act of 2015, could also impact our business.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempt to implement several of the Trump administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored National model, on December 27, 2021 CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures have 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, to encourage importation from other countries and bulk purchasing.

Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

### ***The Foreign Corrupt Practices Act***

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

### ***Additional Regulation***

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

### ***Other Regulations***

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

### **Employees**

As of December 31, 2021, we had 263 employees, 135 of whom hold advanced degrees, including 64 with a Ph.D. and/or M.D. degree. Of these employees, 218 were engaged in research and development activities and 45 were engaged in general and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

### **Human Capital Resources**

We have grown to a team of 263 employees as of December 31, 2021, substantially all of which are full-time employees. All of our employees were employed in the United States. Our highly qualified and experienced employees which includes scientists, physicians and professionals across research, clinical, manufacturing, regulatory, and general and administrative functions are critical to our success. We also leverage temporary workers to provide flexibility for our business needs. During 2021, we added over 57 employees to our team.

We expect to continue to add additional employees in 2022 with a focus on expanding our expertise and capabilities in clinical and preclinical research and development, including an expansion of our internal manufacturing capacity. Our culture is driven by innovation, nimbleness and passion for the work that we do, the people we work with and the patients we serve. As we grow, we continually evaluate our business needs and opportunities and balance hiring top talent internally and leveraging external expertise. Currently, we remain reliant on third-party contract manufacturers and clinical research organizations for our clinical programs.

### **Corporate Information**

We were incorporated in Delaware in December 2014. Our principal executive offices are located at 9390 Towne Centre Drive, Suite 200, San Diego, California 92121, and our telephone number is (858) 779-3100. Our corporate website address is [www.poseida.com](http://www.poseida.com). Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this report is an inactive textual reference only.

### **Emerging Growth Company**

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of

our initial public offering, or IPO, in July 2020, (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 means we have been subject to the reporting requirements of the Exchange Act for twelve calendar months and the market value of our common stock that is held by non-affiliates exceeded \$700.0 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. We refer to the Jumpstart Our Business Startups Act of 2012 in this Annual Report as the “JOBS Act,” and references to “emerging growth company” have the meaning associated with it in the JOBS Act.

## Item 1A. Risk Factors.

*An investment in our common stock is speculative and involves a high degree of risk. You should consider carefully the risks described below, together with the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase, hold or sell shares of our common stock. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled "Special Note Regarding Forward-Looking Statements."*

### **Risks Related to Our Limited Operating History, Financial Position and Capital Requirements**

***We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated any revenue from product sales and may never be profitable.***

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing and protecting our intellectual property portfolio, developing our platform technologies, identifying potential product candidates and undertaking research and development and manufacturing activities, including preclinical studies and clinical trials of our product candidates. All of our product candidates are in early development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. For the years ended December 31, 2021 and 2020, we have incurred a net loss of \$125.0 million and \$129.8 million, respectively. As of December 31, 2021, we had an accumulated deficit of \$406.9 million. We expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.***

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution.

As of December 31, 2021, we had \$206.3 million in cash and cash equivalents. Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operations through at least the next 12 months. However, our current cash and cash equivalents will not be sufficient to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could exhaust our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- scope, progress and results of our ongoing and planned preclinical studies and clinical trials for our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates;
- timing of licensing payments we may be required to make based on the development of our product candidates;
- the number, and development requirements of other product candidates that we may pursue;
- the timing and outcome of regulatory review of our product candidates;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approval;
- our decisions to initiate additional clinical trials, not to initiate any clinical trial or to terminate an existing clinical trial;
- the cost of obtaining raw materials and drug product for clinical trials and commercial supply, which, due to the wide variability in manufacturing costs between autologous and allogeneic product candidates, will also depend on which product candidates progress to future clinical trials;
- whether we decide to partner any of our product candidates with any third parties and the terms of any such partnership or collaboration;
- the cost and timing of establishing and validating our pilot manufacturing facility;
- whether we decide to establish a commercial manufacturing facility for supply of our product candidates; and
- additions or departures of key scientific or management personnel.

Because we do not expect to generate revenue from product sales for many years, if at all, we will need to obtain substantial additional funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. The impact of the COVID-19 pandemic, as well as changes in interest rates and economic inflation on capital markets may affect the availability, amount and type of financing available to us in the future. On August 13, 2021, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, to sell shares of common stock, from time to time, through an “at the market offering” program having an aggregate offering price of up to \$85.0 million through which Cantor would act as sales agent. There can be no assurance that we will meet the requirements to be able to sell securities pursuant to the Sales Agreement, or if we meet the requirements that we will be able to raise sufficient funds on favorable terms. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

***The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

We have an outstanding term loan in the principal amount of \$60.0 million under our loan and security agreement with Oxford Finance LLC, or Oxford. The loan is secured by a lien covering substantially all of our personal property, rights and assets, excluding intellectual property. The loan agreement contains customary affirmative and negative covenants and events of default applicable to us and any subsidiaries. The affirmative covenants include, among others, covenants requiring us (and us to cause our subsidiaries, if any) to maintain governmental approvals, deliver certain financial reports, maintain insurance coverage, keep inventory, if any, in good and marketable condition and protect material intellectual property. The negative covenants include, among others, restrictions on us and our subsidiaries transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. The restrictive covenants of the loan agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. In addition, among other default triggers, Oxford could declare a default upon the occurrence of any event that it interprets as a material adverse change as defined under the loan agreement. If we default under the loan agreement, Oxford may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, Oxford’s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could

cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

### **Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates**

***Our product candidates are in the early stages of development and we have a limited history of conducting clinical trials to test our product candidates in humans.***

We are early in our development efforts and most of our operations to date have been limited to developing our platform technologies, establishing manufacturing capabilities and conducting drug discovery and preclinical studies. In November 2021, we made the decision to wind down clinical development of our P-BCMA-101 program, which was the first of our product candidates to have been tested in humans. We dosed the first patient in a Phase 1 clinical trial of P-PSMA-101 in May 2020, and initiated Phase 1 clinical trials for P-BCMA-ALLO1 and P-MUC1C-ALLO1 in late 2021. As a result, we have limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, and cannot be certain that our clinical trials will be completed on time, that our planned clinical trials will be initiated on time, if at all, that our planned development programs would be acceptable to the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

Because of the early stage of development of our product candidates, our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- successful completion of preclinical studies;
- submission of our INDs or other regulatory applications for our planned clinical trials or future clinical trials and authorizations from regulators to initiate clinical studies;
- successful enrollment in, and completion of, clinical trials and achieving positive results from the trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing manufacturing capabilities or arrangements with third-party manufacturers for clinical supply and, if and when approved, for commercial supply;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- developing and implementing marketing and reimbursement strategies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all; and
- maintaining a continued acceptable safety profile of any product following approval, if any.

If we do not achieve one or more of these requirements in a timely manner, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

***Clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.***

The research and development of drugs and biological products is extremely risky. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain.

The results of preclinical studies and early clinical trials of our product candidates and other products, even those with the same or similar mechanisms of action, may not be predictive of the results of later-stage clinical trials. In particular, it is not uncommon for product candidates to exhibit unforeseen safety or efficacy issues when tested in humans despite promising results in preclinical animal models. In August 2020, we announced the P-PSMA-101 trial was put on clinical hold to assess a patient death. This clinical

hold was lifted in November 2020 with the implementation of protocol amendments intended to increase patient compliance and safety that include modified inclusion and exclusion criteria and frequency of monitoring and laboratory testing. On February 17, 2022, we presented interim results from 14 treated and evaluable patients in our P-PSMA-101 Phase 1 clinical trial. In addition, due primarily to the observation of anti-drug antibodies in some patients in our first clinical trial, P-BCMA-101, we explored additional dosing strategies, such as administering the doses in smaller cycles in the first 30 days and adding rituximab to the preconditioning regimen to potentially suppress any antibody response. If these anti-drug antibodies are neutralizing the product candidate, the activity of P-BCMA-101, or any other product candidate in which anti-drug antibodies neutralize the product candidate, may be limited. To the extent that we choose one of these newer dosing strategies for advancement in any of our clinical trials, it may be on the basis of more limited data as compared to the previously evaluated Phase 1 cohorts. Other than P-BCMA-101 and P-PSMA-101, none of our product candidates have ever been tested in humans. We have only recently initiated clinical trials for our first two allogeneic CAR-T product candidates, P-BCMA-ALLO1, and P-MUC1C-ALLO1. While we have applied learnings from our autologous P-BCMA-101 product candidate in our development of P-BCMA-ALLO1, we cannot be certain that these learnings will be applicable to the allogeneic program or that we will not encounter unexpected results dosing P-BCMA-ALLO1 or P-MUC1C-ALLO1 for the first time in humans. Future results of preclinical and clinical testing of our product candidates are also less certain due to the novel and relatively untested nature of our approach to CAR-T and gene therapy development and related platform technologies. In general, clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

If the results of our clinical trials are inconclusive or if there are safety concerns or adverse events associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Treatment with our oncology product candidates involves chemotherapy and myeloablative treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause other adverse events. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

***We may encounter substantial delays in our clinical trials.***

We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, we cannot begin our planned Phase 1 clinical trials for our liver directed gene therapy candidates until we or our collaborators complete certain preclinical development and submit and receive authorization to proceed under INDs. While we announced FDA clearance for our IND for P-BCMA-ALLO1 in August 2021 and our IND for P-MUC1C-ALLO1 in December 2021, we are dependent on clinical sites to complete startup activities and enroll patients. We announced in August 2020 our P-PSMA-101 trial was put on clinical hold to assess a patient death. In November 2020 we announced that the FDA had lifted the clinical hold based upon our investigation of the event and proposed protocol amendments intended to increase patient compliance and safety. While we have resumed the trial, the clinical hold will delay the ultimate completion of the trial and we cannot guarantee that after resuming the trial, we will not observe

additional patient deaths or encounter other events that cause the P-PSMA-101 trial be suspended or terminated. Finally, the COVID-19 pandemic has impacted clinical trials broadly, including our own, with some sites pausing enrollment and we have experienced a delay in manufacturing at times due to potential exposure. These impacts have caused us to reevaluate the expected timing of clinical milestones and we have and continue to experience delays in site initiation and patient enrollment, and could also experience delays in the manufacture of our product candidates for clinical testing and other difficulties in starting or completing our clinical trials. Other events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical trial operations or study sites;
- failure by our CROs, other third parties or us to adhere to the trial protocol or the FDA's good clinical practices, or GCPs, or applicable regulatory guidelines in other countries;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the treatment sites, including due to a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices, or cGMPs, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a study;
- discovering that product candidates have unforeseen safety issues, undesirable side effects or other unexpected characteristics;
- to the extent that we conduct clinical trials in foreign countries, the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries;
- receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial;
- suspensions or terminations by us, the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, for such trial or by regulatory authorities due to a number of factors, including those described above;
- lack of adequate funding; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to raise capital, generate revenues from product sales and enter into or maintain collaboration arrangements. For example, under certain of our manufacturing agreements for our product candidates we pay a fixed price per month for up to a specified number of manufacturing runs and certain clinical trial services agreements are based on fees that do not vary based on patient enrollment. Therefore, if enrollment in a clinical trial is slowed, certain of our expenses related to the trial would not decrease and therefore the overall costs to complete the trial would increase. In addition, if we make manufacturing changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.***

We have concentrated our research and development efforts on product candidates using our platform technologies, and our future success depends on the successful development of this approach. CAR-T and gene editing in general are newly-emerging fields and our approaches in particular have not been extensively tested over any significant period of time. In particular, while we believe that CAR-T products with higher percentages of T<sub>SCM</sub> cells may be capable of overcoming certain challenges faced by early-generation CAR-T products, we cannot be certain that increasing the percentage of these cells will result in the intended benefits or will not result in unforeseen negative consequences over time, including due to the potential long-term persistence of the modified cells in the body. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates based on our platform technologies in clinical trials or in obtaining marketing approval thereafter, and use of our platform technologies may not ever result in marketable products. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our clinical trials or commercializing any products on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. While CAR-T and gene therapy products have made progress in recent years, only a small number of products have been approved in the United States or other markets, 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 addition, the gene-editing industry is rapidly developing, and our competitors may introduce new technologies that render our technologies obsolete or less attractive. New technology could emerge at any point in the development cycle of our product candidates. As competitors use or develop alternative technologies, any failures of such technologies could adversely impact our programs. For example, some studies have suggested that gene editing using the CRISPR-Cas9 method may increase the risk that the edited cells themselves become cancerous, and in October 2021, discovery of a chromosomal abnormality of unknown clinical significance resulted in a full clinical hold on the programs of one of our competitors utilizing the TALEN method. Regardless of our belief that our non-viral Cas-CLOVER approach to gene editing may avoid some of the issues identified in these studies, it is possible that our approach will be associated with similar risks or that issues encountered with other gene editing techniques will create a negative perception of or increase scrutiny for our technologies and product candidates.

Regulatory requirements governing products created with gene editing technology or involving gene therapy treatment have changed frequently and will likely continue to change in the future. Approvals by one regulatory agency may not be indicative of what any other regulatory agency may require for approval, and there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of gene therapy products and other products created with gene editing technology. For example, under the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines, supervision of human gene transfer trials includes 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. The IBC assesses the safety of the research and identifies any potential risk to 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. Even though we may not be required to submit a protocol for our product candidates through the NIH for review, we will still be subject to significant regulatory oversight by the FDA, and in addition to the government regulators, the applicable IBC and IRB of each institution at which we conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial.

Additionally, adverse developments in clinical trials conducted by others of gene therapy products or products created using genome editing technology, such as products developed through the application of a CRISPR/Cas9 technology, or adverse public perception of the field of gene editing, may cause the FDA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene editing technologies, either of which could materially harm our business. Furthermore, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the development or commercialization of current or future product candidates.

We are also developing allogeneic CAR-T product candidates that are engineered from healthy donor T cells and are intended for use in any patient with certain cancers. Allogeneic versions of CAR-T product candidates is an unproven field of development and is subject to particular risks that are difficult to quantify, including understanding and addressing variability in the quality of a donor's T cells and the patient's potential immune reaction to the foreign donor cells, which could ultimately affect safety, efficacy and our ability to produce product in a reliable and consistent manner. For example, in response to FDA feedback to our IND for P-BCMA-ALLO1, we were required to update certain assay release criteria unique to an allogeneic product candidate. While implementation of

this update has not yet impacted our clinical timelines, there can be no assurance that it, or similar regulatory requirements would not do so in the future, and any such delays could materially and adversely affect our business, financial condition, results of operations and future growth prospects.

***Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.***

To date, we have only tested P-BCMA-101 and P-PSMA-101 in a limited number of patients with cancer and the majority of these clinical trial participants have only been observed for a limited period of time after dosing. As we continue developing our product candidates and initiate clinical trials of our additional product candidates, serious adverse events, or SAEs, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. For example, a significant risk observed in CAR-T product clinical trials is the development of CRS which in some instances resulted in neurotoxicity and patient deaths. While we have observed relatively limited instances of CRS or neurotoxicity in clinical trials of P-BCMA-101 and P-PSMA-101, we may observe greater rates of these or other adverse events in our other CAR-T programs. Should we observe additional or more severe cases of CRS in our clinical trials or identify other undesirable side effects or other unexpected findings depending on their severity, our trials could be delayed or even stopped and our development programs may be halted entirely. In August 2020, we announced our P-PSMA-101 trial was placed on clinical hold to evaluate the death of a patient, which may have been related to treatment with P-PSMA-101. In November 2020 we announced that the FDA had lifted the clinical hold based upon our investigation of the event and proposed protocol amendments intended to increase patient compliance and safety, and we have resumed the trial and we reported interim results on the first 14 patients in February 2022. Despite the clinical hold being lifted, we could observe similar patient deaths or other adverse events that require that the P-PSMA-101 trial be suspended or terminated, which could represent a substantial setback to the program.

Even if our product candidates initially show promise in early clinical trials, the side effects of biological products are frequently only detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit 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 create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- the product may become less competitive;
- we may decide to remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

***Interim, topline and preliminary data from our clinical trials 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, interim or topline 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 as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be 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 interim, topline 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. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available.

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 to be material or otherwise appropriate information to include in our disclosure.

***We may not ultimately receive or realize the potential benefits of orphan drug designation for any of our product candidates.***

We may seek orphan drug designation for certain of our product candidates. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but where there is no reasonable expectation to recover the costs of developing and marketing a treatment drug in the United States. While we previously received orphan drug designation for P-BCMA-101 for the treatment of relapsed/refractory multiple myeloma, we may not receive this designation for P-BCMA-ALLO1 or any other product candidate in the future. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process.

In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition.

***We may seek Regenerative Medicine Advanced Therapy, or RMAT, designation for certain of our product candidates; however, even if granted, such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing approval.***

In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act. An investigational drug is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, 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; (2) it is intended to treat, modify, reverse, or cure a serious disease or condition; and (3) preliminary clinical evidence indicates that the investigational drug has the potential to address unmet medical needs for such disease or condition. While we previously received RMAT designation for P-BCMA-101 for the treatment of multiple myeloma, we may not receive this designation for any other product candidate in the future. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review of BLAs 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 sites, including through expansion of clinical trials, as appropriate. RMAT-designated product candidates that receive accelerated approval may, as determined by the FDA, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records), through the collection of larger confirmatory data sets, or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

RMAT designation does not change the standards for product approval, and there is no assurance that such designation or eligibility for such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

***Our product candidates must meet extensive regulatory requirements before they can be commercialized and any regulatory approval may contain limitations or conditions that require substantial additional development expenses or limit our ability to successfully commercialize the product.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

To date, we have not submitted a BLA or other marketing authorization application to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. Accelerated approval requires the data to indicate the drug candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on 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. In particular, because the FDA has already approved therapies for certain of the indications our product candidates are designed to treat, and because additional drugs may be approved for these indications while we are developing our product candidates, it is difficult to predict whether accelerated approval will be possible for our product candidates at the time we expect to submit a BLA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. In particular, because we are seeking to identify and develop product candidates using new technologies, there is heightened risk that the FDA or other regulatory authorities may impose additional requirements prior to granting marketing approval, including enhanced safety studies or monitoring. Furthermore, as more product candidates within a particular class of products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected product-related side effects may be experienced by participants in our clinical trials or by individuals using biological products similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an application for regulatory approval or other submissions or to obtain regulatory approval in the United States or elsewhere, including due to clinical trial issues encountered as a result of COVID-19 pandemic, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may fail to approve any required companion diagnostics to be used with our product candidates;
- such authorities may find deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we or any of our potential future collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

Even if we eventually complete clinical trials and receive approval to commercialize our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS. The FDA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Manufacturers of our products and manufacturers' facilities are also required to comply with cGMP regulations, which include requirements related to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to continual review and periodic inspections by the FDA and other comparable foreign regulatory authorities for compliance with cGMP regulations.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially and adversely impact our business and prospects.

***Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

If the FDA, EMA or any other comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with cGMPs and GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary product recalls;
- fines, untitled or warning letters or holds on clinical trials;
- refusal by the FDA, the EMA or any other comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Moreover, if any of our product candidates are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about biopharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling.

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

In addition, the policies of the FDA, the EMA and other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements, or if we are unable to maintain regulatory compliance, marketing approval that has been obtained may be lost and we may not achieve or sustain profitability.

***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, or approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA to review and 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 agency 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 may also slow the time necessary for new biologics 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, in response to the global COVID-19 pandemic, the FDA postponed most foreign and domestic inspections of manufacturing facilities and products for several months during 2020 and only resumed them on a risk-based basis, incorporating remote monitoring methods as well. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***We may not be successful in our efforts to identify or discover additional product candidates in the future.***

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited.

**Risks Related to Manufacturing, Commercialization and Reliance on Third Parties**

***We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.***

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our ongoing clinical trials and any future clinical trials of our product candidates. Specifically, CROs, clinical investigators, and consultants play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our 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 are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the 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. 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 stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves to limit the spread of COVID-19, including quarantines and shelter-in-place orders. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash 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 any comparable foreign regulatory authority concludes 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 marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

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

***We or the third parties on which we rely for the manufacturing and supply of certain of our product candidates for use in preclinical testing and clinical trials, may not be able to establish or maintain supply of our product candidates that is of satisfactory quality and quantity.***

We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We rely on third parties for the manufacture of certain of our product candidates for preclinical and clinical testing and may continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We have a pilot manufacturing facility which we are using to develop and manufacture preclinical and clinical material for clinical trials for certain product candidates. We are initially using the facility for the GMP manufacturing of our P-MUC1C-ALLO1 program, however we may encounter delays, quality or other issues as we use our pilot manufacturing facility for clinical supply. Even though the pilot manufacturing facility is validated and qualified, we expect that we will continue to rely on third parties for various manufacturing needs. We currently have limited manufacturing arrangements and expect that each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. Our facilities and quality systems, and those of our third-party contract manufacturers, must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of the COVID-19 pandemic, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third-party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

***Manufacturing gene engineered products is complex and we or our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.***

Manufacturing gene engineered products is complex and may require the use of innovative technologies to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at manufacturing facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we or our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If we or our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***Changes in methods of product candidate manufacturing may result in additional costs or delays.***

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

***Any approved products may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.***

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and physicians may continue to rely on these treatments. Most of our product candidates target mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products 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 availability of coverage and adequate reimbursement from third party payors;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

***We may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.***

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

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 may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services, or CMS, revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

We expect to experience pricing pressures in connection with the sale of any 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 medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Additionally, we or collaborators may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we may seek for our product candidates. While we have not yet developed any companion diagnostic tests for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

***Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which 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 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 the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-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 generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

***If the market opportunities for any of our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.***

We are focused initially on the development of treatments for cancer. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.***

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing 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 future products 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 educate an adequate numbers of physicians regarding the benefits of any product, once approved;
- 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 portfolios; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market any future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***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.

## Risks Related to Our In-Licenses and Other Strategic Agreements

***We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our platform technologies and resulting product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.***

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations for achievement of certain milestones and royalties on product sales, negative covenants and other material obligations. For example, with respect to P-PSMA-101, we have licensed Centyrin binders under an agreement with Janssen Biotech Inc., or Janssen, with respect to P-BCMA-ALLO1, we have licensed heavy-chain-only binders under an agreement with TeneoBio, Inc., or TeneoBio, with respect to P-MUC1C-ALLO1, we have licensed a binder under our agreement with Genus Oncology, LLC, or Genus, with respect to our dual CAR programs and other allogeneic preclinical programs we have licensed and may continue to license binders under our agreements with TeneoBio, and with respect to our Cas-CLOVER gene editing technology, which we use in the manufacture of P-BCMA-ALLO1, P-MUC1C-ALLO1, P-CD19CD20-ALLO1 and future allogeneic products, we have licensed certain intellectual property under an agreement with Helmholtz-Zentrum München—Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH. If we fail to comply with the obligations under our license agreements, including as a result of COVID-19 impacting our operations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may not be able to develop, manufacture, market or sell the products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

***We may not realize the benefits of any acquisitions, in-license or strategic alliances that we enter into.***

We have entered into in-license agreements with multiple licensors and in the future may seek and form strategic alliances, create joint ventures or collaborations, or enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially

adverse impacts on our or the counterparty's operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

***Our collaborators may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop or commercialize certain of our product candidates and our financial condition and operating results.***

We have, with respect to our collaboration with Takeda, and will likely have, with respect to any additional collaboration arrangements with any third parties, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. For example, while we expect to collaborate with Takeda on the development of up to six *in vivo* gene therapy programs, only two such programs have been designated by Takeda and we cannot guarantee that Takeda will elect to pursue development of additional gene therapy programs under the collaboration, which would limit the potential payments we may receive under the agreement. In general, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements and otherwise to comply with their contractual obligations.

Any of our existing or future collaborations may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. In addition, the terms of any such collaboration or other arrangement may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product or product candidate or research program under collaboration and the payment we receive from our partner may be insufficient to cover the cost of this development. For example, under the Takeda Collaboration Agreement, we are obligated to perform certain platform development activities at our own cost.

Conflicts may arise between us and our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the division of development responsibilities or expenses, development plans, the interpretation of financial provisions, or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a collaborator could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a collaborator could delay or prevent the development or commercialization of our product candidates.

Further, we are subject to the following additional risks associated with our current and any future collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail:

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may fail in their development or commercialization efforts with our product candidate, in which event the development and commercialization of such product candidate could be delayed or terminated;
- collaborators may delay clinical trials, insufficiently fund a clinical trial program, stop a clinical trial, 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 products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may fail to successfully design or implement clinical trials and may collect and publish clinical trial data that are inconsistent with, or contradictory to, our clinical trial results;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may deviate from established guidelines, instructions, or best practices for product handling and storage, which may compromise the safety, purity, potency, and effectiveness of our products and potentially result in the occurrence of serious adverse events in patients using our products;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- we could experience reductions in the payments we believe are due to us pursuant to the applicable collaboration arrangement;
- collaborators could take actions inside or outside our collaboration that could negatively impact our rights or benefits under the applicable collaboration; or
- our collaborators may be unwilling to keep us informed regarding the progress of their development and commercialization activities or to permit public disclosure of their progress.

***We may wish to form additional collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.***

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of certain product candidates, including in territories outside the United States or for certain indications. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Third party collaborations generally require us to relinquish some or all of the control over the future success of the applicable product candidates to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, 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 certain product candidates, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for certain product candidates, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing 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 our product candidates or bring them to market and generate product revenue.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

### **Risks Related to Our Industry and Business Operations**

***The COVID-19 pandemic continues to adversely impact our business, including our clinical trials, supply chain and business development activities.***

In March 2020, the World Health Organization made the assessment that a novel strain of coronavirus, SARS-CoV-2, a novel strain of coronavirus, commonly referred to as COVID-19 had become a global pandemic. In March 2020, the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the United States have taken aggressive actions to reduce the spread and ameliorate the impact of the disease, including limiting non-essential gatherings of people and non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions) and have also implemented multi-step policies with the goal of re-opening such states and municipalities. As a result of these actions and in an effort to ensure the safety of employees during the pandemic, a majority of our employees are at least partially currently telecommuting, which has impacted certain of our operations and may continue to do so over the long term. We may experience further limitations on employee resources in the future, including because of sickness of employees or their families. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 continues to negatively impact

productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain and impair our ability to execute our business development strategy. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, and our operations may be further limited or curtailed.

As COVID-19 continues to spread and new variants emerge, we expect to experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling and maintaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire 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; and
- refusal of the FDA to accept data from clinical trials.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Our clinical trials have been, and we expect will continue to be, affected by the COVID-19 pandemic. For example, some of our clinical trial sites have slowed down or stopped further enrollment of new patients in clinical trials, denied access to site monitors and otherwise curtailed certain operations. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted. Our ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies. We and our CROs have also made certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

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 could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

Furthermore, quarantines, shelter-in-place and similar government orders related to COVID-19 or other infectious diseases could cause a pause in manufacturing in both our external CMO's and our pilot manufacturing facility, which could significantly delay the supply of clinical material. We have experienced some cancelled or delayed manufacturing operations at our CMO's due to staffing issues related to COVID-19. In addition, even though our pilot manufacturing facility is fully operational, government orders

or staffing issues related to COVID-19 illness could prevent us from operating the facility as intended. These events could delay our ability to manufacture clinical-scale materials for certain of our product candidates and otherwise delay the development of certain of our product candidates.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. 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 risks described in this “Risk Factors” section, such as those relating to the timing and results of our clinical trials and our financing needs.

***We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.***

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. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance of \$5.0 million per occurrence and \$5.0 million aggregate limit. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, 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 and when we obtain marketing approval for product candidates, we intend to expand our 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. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claims, 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.

Patients with cancer and other diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates, such as the patient death that occurred in our Phase 1 P-PSMA-101 trial. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

***We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct substantially all of our operations at our facilities in San Diego. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Other than for Dr. Ostertag, our Executive Chairman, we do not maintain “key person” insurance policies on the lives of any of our executive officers. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. We have experienced higher than normal turnover in the past year, due to the increasingly competitive hiring market in the biotechnology industry and if we cannot retain our existing employees and hire new employees to combat the impact of attrition, our operations may be adversely affected.

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

As of December 31, 2021, we had 263 employees. As we advance our research and development programs, we may be required to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, manufacturing, quality, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates, both as monotherapy and in combination with other intra-portfolio product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, 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.

***We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.***

The development and commercialization of new products is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer and gene therapies for inherited genetic disorders. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Moreover, with the proliferation of new drugs and therapies into oncology and genetic disorders, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and

new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical.

Other products in the same class as some of our product candidates have already been approved or are further along in development. As more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in those class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Specifically, there are many companies pursuing a variety of approaches to CAR-T therapies, including Adaptimmune Therapeutics plc, Allogene, Inc., Astellas Pharma, Inc., Autolus Ltd., Bellicum Pharmaceuticals Inc., Bluebird Bio, Inc., Cellectis S.A., Janssen Pharmaceuticals Inc., Juno Therapeutics, Inc. (acquired by Celgene Corporation, now a Bristol-Myers Squibb company), Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Legend Biotech Corporation, Novartis AG and Takeda. Immunotherapy and gene therapy approaches are further being pursued by many smaller biotechnology companies as well as larger pharmaceutical companies. We also face competition from non-cell-based or other gene therapy treatments offered by companies such as Amgen Inc., AstraZeneca plc, Beam Therapeutics, Inc, Bristol-Myers Squibb Company, F. Hoffman-La Roche AG, Generation Bio, Inc., GlaxoSmithKline plc, Merck & Co., Inc. PassageBio, Inc. and Pfizer Inc. Many of our competitors, either alone or with their collaboration partners, have substantially greater financial, technical and other resources, such as larger research and development staff and/or greater expertise in research and development, manufacturing, preclinical testing and conducting clinical trials.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, and availability of reimbursement. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

***We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters.***

Our headquarters, main research facility and pilot manufacturing facility are located in San Diego, California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service providers' disaster recovery and business continuity plans, which could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans, business, financial condition or results of operations.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused U.S. federal net operating losses, or NOLs, for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the federal tax laws.

As of December 31, 2021, we had \$23.3 million of U.S. federal NOLs that will begin to expire in 2032, and \$329.9 million of U.S. federal NOLs that can be carried forward indefinitely under current law. As of December 31, 2021, we also had aggregate U.S.

federal orphan drug credits and research and development, or R&D, credits of approximately \$33.2 million. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards, R&D credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

***Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the EU, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (1) introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (5) established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% 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; (6) extended manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (7) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability; (8) created a licensure framework for follow on biologic products; (9) established a 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; and (10) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, the legislation enacted in 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act’s mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act 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 Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It

is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business or financial condition.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to legislative amendments to the statute, the Infrastructure Investment and Jobs Act, the BBA and the Coronavirus Aid, Relief, and Economic Security Act, will remain in effect through 2031 unless additional Congressional action is taken. These reductions have been suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians, also referred to as the Quality Payment Program, under the Medicare Access and CHIP Reauthorization Act of 2015. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare Program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. In addition, new laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempt to implement several of the Trump administration's proposals. As a result, the FDA released a final rule and guidance in September 2020 implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives.

At the state level, legislatures have 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.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs once marketing approval is obtained.

Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. The requirements may differ across the EU Member States. Also, at

national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

***We are subject to applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our current and future arrangements with clinical investigators, third-party payors, healthcare provider and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we research, market, sell and distribute our products. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, and purchasers, on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but these exceptions and safe harbors are narrowly drawn. Practices that are alleged to be intended to induce prescribing, purchases or recommendations, or include any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor;
- federal civil and criminal false claims laws, such as the civil False Claims Act, or FCA, which can be enforced by private citizens through civil qui tam actions, and the Civil Monetary Penalties Law prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with, among other things their alleged off-label promotion of drugs, engaging in improper consulting arrangements with physicians, concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, 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. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program to report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and

chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- analogous state, local and foreign laws and regulations, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers, state and local laws that require the registration of pharmaceutical sales representatives, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

We may also be subject to federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, some of which include provisions of stock options, including some who could influence the use of our product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws.

Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to significant investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform technologies and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued which protect our product candidates or their intended uses or which effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including as a result of the COVID-19 pandemic impacting our or our licensors' operations. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our

research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Composition of matter patents for biological and pharmaceutical products such as CAR-based product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, reexaminations, or *inter partes* review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, 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 products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is 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 products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party’s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

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

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will

impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, including due to the impact of the COVID-19 pandemic on our business operations, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, including due to the impact of the COVID-19 pandemic on our licensors' business operations, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described herein. If we or our licensor fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

***In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.***

We currently have rights to intellectual property covering our product candidates and other proprietary technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

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 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.

Moreover, some of our owned and in-licensed patents or patent applications or future patents are or may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

***We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.***

We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own, or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

***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. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- 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;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

***If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. For example, in early 2019, we received a letter from a third party alleging that we have used materials received from the third party in an unauthorized manner and stating a belief that we will infringe certain patents relating to the use of a safety switch in our CAR-T products. While we have denied that we used any of the third party's materials in an unauthorized manner and believe that the patents will not be infringed, are invalid, or both, we cannot predict whether the third party will persist in its allegations or whether litigation will ensue. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have

produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***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 or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/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, non-enablement or insufficient written description. 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. 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.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing 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 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 shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we

ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

***Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.***

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. As such, our intellectual property rights in some countries outside the United States can be less extensive than those in the United States and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or technology and may export otherwise infringing products or technology to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any such lawsuits that we initiate and the damages and other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit

our potential revenue opportunities. 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.

***Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (1) file any patent application related to our product candidates and other proprietary technologies we may develop or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making 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 our existing patents and patents that we might obtain in the future. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, 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.***

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

***We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidate, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

***We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on 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.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment 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.

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, a patent's life can be increased based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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.

## Risks Related to Our Common Stock

***The market price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance and you could lose all or part of your investment.***

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- the published opinions and third-party valuations by banking and market analysts;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float;
- the ongoing and future impact of the COVID-19 pandemic and actions taken to slow its spread; and
- any other factors discussed in this Annual Report on Form 10-K.

In addition, the stock markets in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology and gene therapy companies. Stock prices of many of these companies have fluctuated in a manner unrelated or disproportionate to their operating performance, and we have in the past experienced volatility that has been unrelated or disproportionate to our operating performance. From January 1, 2021 through March 4, 2022, the closing price of our common stock has ranged between \$3.27 and \$11.91 per share. The trading prices for common stock of other biopharmaceutical companies have also been highly volatile as a result of the COVID-19 pandemic and anticipated increase in interest rates. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of March 4, 2022, our executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 70% of our voting stock. Therefore, these stockholders have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

In addition, Dr. Ostertag, our Executive Chairman, a member of our board of directors and the beneficial owner of approximately 15% of our voting stock as of March 4, 2022, is the sole director of Demeetra AgBio, Inc., or Demeetra, serves as its President and Secretary and together with his affiliated entities, owns on a fully-diluted basis, 63% of its capital stock. Further, Dr. Ostertag is also a member of the board of directors of Hera Testing Laboratories, Inc., or Hera, and served as its Chief Executive Officer from inception until July 2015 and, together with his affiliated entities, owns on a fully-diluted basis, 42% of its capital stock.

As a result, the interests of Dr. Ostertag may not be aligned with the interests of you and our other stockholders with respect to our relationships with Hera and Demeetra, and he may from time to time be incentivized to take certain actions that benefit his interests in those other entities and that you and our other stockholders do not view as being in your interest as investors in our company.

***If we fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We may discover material weaknesses in our system of internal financial and accounting controls and procedures in the future that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

#### **General Risk Factors**

***We will continue to incur significantly 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.***

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, we are subject to the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and various requirements the Nasdaq Global Select Market have imposed on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period and up to five years from the completion of our IPO. We intend to continue to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. 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 costlier. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. We estimate that we annually incur approximately \$3.0 million to \$4.0 million in additional expenses to comply with the requirements imposed on us as a public company.

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

***Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.***

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. 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 confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed.

While we have not experienced any such system failure, accident or security breach to date, we cannot be certain that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us.

For example, if we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements and/or oversight, restrictions on processing data (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, interruptions in our operations (including availability of data), financial loss; and other

similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

***Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Biden administration and Congress have proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flows, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

***Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.***

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. For example, The California Consumer Privacy Act of 2018, or CCPA, imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to \$7,500 per violation). Further, it is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, which imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. If we violate HIPAA, we may be subject to significant penalties. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Internationally, virtually every jurisdiction in which we operate has established its own data security and privacy legal framework that may also apply to health-related and other personal information obtained outside of the United States, including but not limited to the European Union, or EU. The unstable nature of EU's data protection landscape may result in possible significant operational costs for internal compliance and risk to our business. While we could take steps to mitigate the impact on us, such as implementing standard contractual clauses, the efficacy and longevity of these mechanisms remains uncertain. In addition, the EU has adopted the General Data Protection Regulation, or GDPR, which went into effect on May 25, 2018 and contains numerous requirements and changes from existing EU law, including more robust obligations on data controllers and data processors, and heavier documentation requirements for data protection compliance programs by companies. Specifically, the GDPR contains numerous privacy-related changes for companies operating in the EU, including greater control for data subjects (e.g., the "right to be forgotten"), increased data portability for EU consumers, data breach notification requirements, and increased fines. In particular, under the GDPR, fines of up to 20 million euros or up to 4% of the annual global revenue of the noncompliant company, whichever is greater, could be imposed for violations of certain of the GDPR's requirements. The GDPR requirements would apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information.

Compliance with the GDPR may cause us to incur substantial operational costs or require us to change our business practices. Despite our efforts to bring practices into compliance with the GDPR, we may not be successful either due to internal or external factors such as resource allocation limitations or a lack of vendor cooperation. Non-compliance could result in proceedings against us by governmental entities, customers, data subjects, or others. We may also experience difficulty retaining or obtaining new European or multi-national customers due to the legal requirements, compliance cost, potential risk exposure, and uncertainty for these entities,

and we may experience significantly increased liability with respect to these customers pursuant to the terms set forth in our engagements with them. We may find it necessary to establish systems to maintain personal data originating from the EU in the European Economic Area, which may involve substantial expense and distraction from other aspects of our business. In the meantime, there could be uncertainty as to how to comply with EU privacy law. Separately, the United Kingdom's withdrawal from the EU could also lead to further legislative and regulatory changes and increase our compliance costs. In particular, the United Kingdom has transposed the GDPR into domestic law with a UK version of the GDPR taking effect from January 2021 (after the end of the transitional period) which could expose us to two parallel regimes each with the power to fine up to the greater of either 4% of global revenue, or Euro 20,000,000 (for the EU) or £17,500,000 (for the UK).

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations which could impact our compliance posture. Failure to comply, or any perceived failure to comply, with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties investigations, fines, audits, and inspections), private litigation (including class-related claims), breach reporting requirements, additional reporting requirements and/or oversight, bans on processing personal data, orders to destroy or not use personal data, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, 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. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers, interruptions or stoppages in our business operations (including, as relevant, clinical trials), inability to process personal data or to operate in certain jurisdictions, expenditure of time and resources to defend any claim or inquiry, or revision or restructuring of our operations.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.***

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, or collectively, Trade Laws, prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential

liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently 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. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy has been and may continue to be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2020 Equity Incentive Plan, or the 2020 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2021 through January 1, 2030, in an amount equal to the lesser of (i) 5% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase, or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1st. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

***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 pharmaceutical 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.

***If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock could be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if the clinical trials and operating results fail to meet the expectations of analysts, the trading price for our common stock would be negatively affected. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure 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 or internal 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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. 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.

***Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.***

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

***We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an “emerging growth company” as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- 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;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an “emerging growth company” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30 and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

***Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.***

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other 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 exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board 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 a majority vote of our entire board of directors, the chairman of our board of directors or our Chief Executive Officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply 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.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

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

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (4) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (5) any

action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (6) any action asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

We currently lease approximately 87,000 square feet of manufacturing, office and laboratory space in San Diego, California under a lease that expires on December 31, 2029, which includes a pilot manufacturing facility adjacent to our office and laboratory space. We believe our existing leased space is sufficient to meet our facilities needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

**Item 3. Legal Proceedings.**

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

**Item 4. Mine Safety Disclosures.**

Not applicable.

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

**Market Information**

Our common stock, par value \$0.0001 per share, is traded on The Nasdaq Global Select Market under the symbol “PSTX.”

**Holders of Record**

As of March 4, 2022, there were approximately 81 stockholders of record of our common stock. Certain shares are held in “street” name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

**Dividend Policy**

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. In addition, our loan agreement with Oxford governing our indebtedness contains restrictions on our ability to declare and pay cash dividends on our capital stock.

**Securities Authorized for Issuance under Equity Compensation Plans**

The information called for by this item is incorporated by reference to our definitive proxy statement for the 2021 Annual Meeting of Stockholders. See Part III, Item 12 “Security Ownership of Certain Beneficial Owners and Management.”

**Recent Sales of Unregistered Securities**

None.

**Use of Proceeds**

We completed our IPO pursuant to a Registration Statement on Form S-1 (File No. 333-239321) that was declared effective on July 9, 2020 and registered an aggregate of 16,100,000 shares of our common stock. On July 14, 2020, we sold 14,000,000 shares of our common stock at a public offering price of \$16.00 per share for an aggregate gross offering price of \$224.0 million.

The net proceeds to us after deducting underwriting discounts and commissions of \$15.7 million and net offering expenses of \$2.6 million were \$205.7 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our IPO were held in cash and cash equivalents and short-term investments, primarily bank money market accounts. Through December 31, 2021, we have used approximately \$47.0 million of the net proceeds from our IPO. There has been no material change in the planned use of proceeds from our IPO from those disclosed in the Registration Statement.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

**Item 6. [Reserved]**

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading “Forward-Looking Statements” in this Annual Report on Form 10-K. You should review the disclosure under the heading “Risk Factors” in this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.*

### Overview

We are a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next-generation cell and gene therapeutics with the capacity to cure. We were incorporated in December 2014 and subsequently spun out from Transposagen, a company that has been developing gene engineering technologies since 2003. Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, in-licensing, developing and acquiring intellectual property rights and establishing and protecting our intellectual property portfolio, developing our gene engineering technologies, identifying potential product candidates and undertaking research and development and manufacturing activities, including preclinical studies and clinical trials of our product candidates, and engaging in strategic transactions. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

We have funded our operations primarily through the sale of equity. Since our inception, we have raised an aggregate of \$334.3 million of gross proceeds from the sale of shares of our redeemable convertible preferred stock, received \$60.0 million of gross proceeds from borrowings under our loan agreement and received an aggregate of \$23.8 million in grant funding from the California Institute of Regenerative Medicine, or CIRM. On July 14, 2020, we completed our initial public offering, or the IPO, pursuant to which we issued and sold 14,000,000 shares of common stock for gross proceeds of \$224.0 million. As of December 31, 2021, we had cash, and cash equivalents of \$206.3 million. We do not have any product candidates approved for sale and have not generated any revenue from product sales. Since our inception, we have incurred significant operating losses and expect to continue to incur significant operating losses for the foreseeable future. Our net losses were \$125.0 million and \$129.8 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of \$406.9 million.

We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac DNA Delivery System, Cas-CLOVER Site-specific Gene Editing System and nanoparticle and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics.

Within cell therapy, we believe our technologies allow us to create product candidates with engineered cells that engraft in the patient’s body and drive lasting durable responses that may have the capacity to result in single treatment cures. Our CAR-T therapy portfolio consists of both autologous and allogeneic, or off-the-shelf, product candidates. We are advancing a broad pipeline and have multiple CAR-T product candidates in the clinical phase in both hematological and solid tumor oncology indications. Within gene therapy, we believe our technologies have the potential to create next-generation therapies that can deliver long-term, stable gene expression that does not diminish over time and that may have the capacity to result in single treatment cures.

The following chart summarizes our current product candidate portfolio for CAR-T in Oncology:

Indication	Candidate	Discovery	Preclinical	IND-Enabling	Phase 1	Phase 2	
<b>CAR-T FOR ONCOLOGY</b>							
<b>MULTIPLE MYELOMA</b>	P-BCMA-ALLO1	Allo					
	P-BCMACD19-ALLO1	Allo					
<b>PROSTATE CANCER</b>	P-PSMA-101	Auto					
	P-PSMA-ALLO1	Allo					
<b>SOLID TUMOR</b>	P-MUC1C-ALLO1	Allo					
	Dual CAR (Undisclosed)	Allo					
<b>B - CELL</b>	P-CD19CD20-ALLO1	Allo					

Our most advanced investigational clinical programs are:

- **P-PSMA-101**, which is an autologous CAR-T product candidate targeting prostate-specific membrane antigen, or PSMA, being developed to treat patients with metastatic castrate-resistant prostate cancer, or mCRPC. We are currently evaluating P-PSMA-101 in a Phase 1 clinical trial. We presented encouraging preliminary results from our Phase 1 clinical trial of P-PSMA-101 in our first solid tumor indication on February 17, 2022 at ASCO-GU and may provide a further clinical update in the second half of 2022 or early 2023.
- **P-BCMA-ALLO1**, which is a fully allogeneic CAR-T product candidate targeting BCMA, being developed to treat relapsed/refractory multiple myeloma patients. Our investigational new drug application, or IND, for this program was cleared by the FDA in August 2021 and we expect initial clinical data from our Phase 1 in the second half of 2022. P-BCMA-ALLO1 follows our first BCMA targeted program, P-BCMA-101, which was an autologous program, and we plan to continue using the learnings from that program in this second-generation approach.
- **P-MUC1C-ALLO1**, which is a fully allogeneic CAR-T product candidate for multiple solid tumor indications. We believe P-MUC1C-ALLO1 has the potential to treat a wide range of solid tumors derived from epithelial cells, such as breast, colorectal, lung, ovarian, pancreatic and renal cancers, as well as other cancers expressing a cancer-specific form of the Mucin 1 protein, or MUC1-C. Our IND for this program was cleared by the FDA in December 2021 and we expect initial clinical data from our Phase 1 clinical trial in the second half of 2022. P-MUC1C-ALLO1 is the first program for which clinical product will be sourced from our internal pilot manufacturing facility.

We manufacture these product candidates using our non-viral piggyBac DNA Delivery System. Our fully allogeneic CAR-T product candidates are developed using well-characterized cells derived from a healthy donor as starting material with the goal of enabling treatment of potentially hundreds of patients from a single manufacturing run. Doses are cryopreserved and stored at treatment centers for future off-the-shelf use. In addition, our allogeneic product candidates use our proprietary Cas-CLOVER site-specific Gene Editing System to reduce or eliminate reactivity, as well as our booster molecule technology for manufacturing scalability.

Our most advanced preclinical cell therapy program is:

- **P-CD19CD20-ALLO1**, which is a fully allogeneic CAR-T product candidate for B-cell hematological indications. This is our first Dual CAR program, which contains two fully functional CAR molecules to target cells that express at least one of the two intended targets. We believe that our ability to include two fully functional CAR molecules into a T cell could provide a competitive advantage compared to current therapies. We anticipate an IND filing and initiation of a Phase 1 clinical trial in the first half of 2023.

The following chart summarizes our current product candidate portfolio in gene therapy:

Indication	Candidate	Discovery	Preclinical	IND-Enabling	
<b>GENE THERAPIES</b>					
ORNITHINE TRANSCARBAMYLASE DEFICIENCY (OTC)	P-OTC-101				
HEMOPHILIA A	P-FVIII-101				
LIVER-DIRECTED #2	UNDISCLOSED				
LIVER-DIRECTED #3	UNDISCLOSED				
LIVER-DIRECTED #4	UNDISCLOSED				
HSC-DIRECTED #1	UNDISCLOSED				
HSC-DIRECTED #2	UNDISCLOSED				

Our gene therapy product candidates have been developed by utilizing our piggyBac technology together with AAV to overcome the major limitations of traditional AAV gene therapy. We believe that our approach can result in integration and long-term stable expression at potentially much lower doses than AAV technology alone, thus also conferring cost and tolerability benefits. Our eventual goal is to completely replace AAV with our nanoparticle technology, freeing future product development in gene therapy of AAV limitations.

Our most advanced gene therapy programs are:

- **P-OTC-101**, which is a liver-directed gene therapy combining piggyBac technology with AAV and nanoparticles for the *in vivo* treatment of Ornithine Transcarbamylase, or OTC, deficiency. OTC deficiency is an often fatal or morbid urea cycle disease caused by congenital mutations in the OTC gene with a high unmet medical need. We are currently evaluating whether to modify the P-OTC-101 program to move completely to our non-viral nanoparticle delivery system. A decision as to whether to pursue the fully nanoparticle or hybrid approach going forward is expected by mid-2022.
- **P-FVIII-101**, which is a liver-directed gene therapy combining piggyBac technology with our nanoparticle delivery technology for the *in vivo* treatment of Hemophilia A. Hemophilia A is a bleeding disorder caused by a deficiency in Factor VIII production with a high unmet need. Our P-FVIII-101 program is included in the collaboration and license agreement, or the Takeda Collaboration Agreement, with Takeda Pharmaceuticals USA, Inc., or Takeda, and Takeda will be responsible for all future development costs.

We expect our expenses and losses to increase substantially for the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates, including P-PSMA-101, P-BCMA-ALLO1, and P-MUC1C-ALLO1, and begin to commercialize any approved products. While we anticipate an overall increase in development costs as we continue to expand the number of product candidates in our pipeline and pursue clinical development of those candidates, we expect a decrease in our development costs for our BCMA programs as we are transitioning to our allogeneic platform. In addition, all development costs related to partnered gene therapy programs will be reimbursed by Takeda. We also expect increases related to an anticipated increase in personnel, accounting, audit, legal, regulatory and consulting services, and costs associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer insurance, investor and public relations activities and other expenses associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

The manufacturing process for our allogeneic product candidates is nearly identical to the process for our autologous product candidates, except for the gene editing and related steps. We work with a number of third-party contract manufacturing organizations for production of our product candidates. We also work with a variety of suppliers to provide our manufacturing raw materials including media, DNA and RNA components. We have completed construction of an internal pilot GMP manufacturing facility in San Diego, California adjacent to our headquarters to develop and manufacture preclinical materials and clinical supplies of our product candidates for Phase 1 and Phase 2 clinical trials in the future. We commenced GMP activity in the third quarter of 2021, however we expect that we will continue to rely on third parties for various manufacturing needs. In the future, we may also build one or more commercial manufacturing facilities for any approved product candidates.

#### Collaboration Agreements

In October 2021, we entered into the Takeda Collaboration Agreement, pursuant to which we granted to Takeda a worldwide exclusive license under our piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms to research, develop, manufacture and commercialize gene therapy products for certain indications, including Hemophilia A. We will collaborate with Takeda to initially develop up to six *in vivo* gene therapy programs and

Takeda also has an option to add two additional programs to the collaboration. We are obligated to lead research activities up to candidate selection, after which Takeda is obligated to assume responsibility for further development, manufacturing and commercialization of each program.

Under the Takeda Collaboration Agreement, Takeda made an upfront payment to us of \$45.0 million. Takeda is also obligated to provide funding for all collaboration program development costs including our P-FVIII-101 program; provided that we are obligated to perform certain platform development activities at our own cost. Timelines for P-FVIII-101 and other programs subject to the Takeda Collaboration Agreement will be driven by Takeda. Under the Takeda Collaboration Agreement, we are eligible to receive preclinical milestone payments that could potentially exceed \$82.5 million in the aggregate if preclinical milestones for all six programs are achieved. We are also eligible to receive future clinical development, regulatory and commercial milestone payments of \$435.0 million in the aggregate per target, with a total potential deal value over the course of the collaboration of up to \$2.7 billion, if milestones for all six programs are achieved and up to \$3.6 billion if the milestones related to the two optional programs are also achieved. We are entitled to receive tiered royalty payments on net sales in the mid-single to low double digits, subject to certain standard reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the latest of the expiration of the licensed patents covering such product in such country, ten years from first commercial sale of such product in such country, or expiration of regulatory exclusivity for such product in such country.

### In-License Agreements

Below is a summary of our key license agreements. For a more detailed description of these and our other license agreements, see the section titled “Business—In-License Agreements” and Note 11 to our consolidated financial statements included in this Annual Report.

- *License Agreement with Janssen Biotech Inc.*, or the Janssen Agreement, pursuant to which we obtained exclusive worldwide rights to research, develop, manufacture and commercialize pharmaceutical products comprising autologous CAR-modified T-cells or any CAR-modified natural killer or CAR-modified natural-killer-like cells expressing certain Centyrin molecules CAR-modified for the treatment or prevention of any disease in humans. This is the binding technology we use in our P-PSMA-101 product candidate. Under the Janssen Agreement, we also have the right to screen Janssen’s Centyrin library for agents that bind or modify targets of interest for our internal research and development purposes for potential use in a licensed product.

Pursuant to the Janssen Agreement, we are required to pay Janssen up to an aggregate of \$75.8 million upon the achievement of certain clinical, regulatory and sales milestones for the first licensed product and up to an aggregate of \$46.8 million upon the achievement of certain clinical, regulatory and sales milestones for each licensed product thereafter. We are also obligated to pay, on a product-by-product and country-by-country basis, royalties in the low single-digit percentage range on annual net sales, with the royalty rates varying depending on if there is a valid claim present within the licensed patent rights covering the licensed product in the applicable country in which the net sales occur. The royalty rates are subject to reduction upon certain events.

- *2017 Commercial License Agreement with TeneoBio, Inc.*, or the 2017 TeneoBio Agreement, pursuant to which we obtained exclusive worldwide rights to use and develop pharmaceutical products comprising allogeneic T-cells expressing a CAR molecule containing certain heavy chain sequences provided by TeneoBio for the treatment of human disease. We use this heavy-chain-only binder in our P-BCMA-ALLO1 product candidate.

Pursuant to the 2017 TeneoBio Agreement, we are required to pay TeneoBio up to an aggregate of \$20.5 million upon the first achievement of certain clinical and regulatory milestones for any allogeneic product and up to an aggregate of \$20.5 million upon the first achievement of certain clinical and regulatory milestones for any autologous product. We are also obligated to pay, on a product-by-product and country-by-country basis, a royalty in the low single-digit percentage on net sales of any licensed products.

- *2018 Commercial License Agreement with TeneoBio, Inc.*, or the 2018 TeneoBio Agreement, for the development and use of TeneoBio’s human heavy-chain-only antibodies in CAR-T cell therapies. Under the terms of the 2018 TeneoBio Agreement, we have the option to obtain exclusive rights to research, develop and commercialize up to a certain number of targets.

Pursuant to the 2018 TeneoBio Agreement, we are required to pay additional fees in the low- to mid-six figure dollar range upon (1) selecting exclusivity for a particular target, which restricts TeneoBio from licensing that particular target to a third party for a period of time, (2) continuing exclusivity for any selected target on each anniversary thereafter and (3) exercising our commercial option for each target. We are required to pay TeneoBio up to an aggregate of \$31.0 million upon the first achievement of certain clinical and regulatory milestones for each licensed product. We are also obligated to

pay, on a product-by-product and country-by-country basis, a low single-digit percentage royalty on net sales of any licensed products. The royalty rate is subject to reduction upon certain events.

- *License Agreement with Genus Oncology, LLC*, or the Genus Agreement, pursuant to which we obtained an exclusive worldwide license under certain patents and a non-exclusive worldwide license under certain know-how controlled by Genus to research, develop and commercialize pharmaceutical products incorporating CAR cells expressing antibodies and derivatives thereof targeting MUC1-C, or a Genus licensed product, and a non-exclusive worldwide license under certain patents and know-how controlled by Genus to research, develop and commercialize companion diagnostics for the treatment, prevention and palliation of human diseases and conditions. We use a Genus antibody or derivative thereof targeting MUC1-C as a binder in our P-MUC1C-ALLO1 product candidate.

Pursuant to the Genus Agreement, we are required to pay Genus up to an aggregate of \$71.0 million upon first achievement of certain clinical, regulatory and sales milestones for any Genus licensed product and companion diagnostics. We are also obligated to pay, on a product-by-product and country-by-country basis, tiered royalties in the low to mid-single-digit percentage on net sales of any Genus licensed products and related companion diagnostics. The royalty rate is subject to reduction upon certain events.

### **CIRM Grant Funding**

In 2017, we were granted an award in the amount of \$19.8 million from California Institute of Regenerative Medicine, or CIRM, to support our clinical trial for P-BCMA-101. Through December 31, 2021, we have received a total of \$19.7 million from this grant and we may receive up to \$0.1 million in future grant payments. In 2018, we were granted an additional award in the amount of \$4.0 million from CIRM to support our preclinical studies for P-PSMA-101, of which we have received all proceeds from this grant. The terms of these awards include an option to repay the grant or convert it to a royalty obligation upon commercialization of the program. Based upon the terms of the grant agreements, we record proceeds as a liability when received. In the fourth quarter of 2021, we made the decision to wind down clinical development of the P-BCMA-101 program, however there is no obligation to repay the amounts associated with the P-BCMA-101 program and derecognized the respective liability and recorded such amount in other income during the year ended December 31, 2021.

### **Components of Our Results of Operations**

#### **Revenues**

##### *Collaboration Revenue*

Collaboration revenue consists of revenue recognized from our collaboration and license agreement with Takeda and reflects the timing and pattern in which we deliver the contractual deliverables to Takeda.

#### **Operating Expenses**

##### *Research and Development*

Research and development expenses consist primarily of external and internal costs incurred for our research and development activities, including development of our platform technologies, our drug discovery efforts and the development of our product candidates.

External costs include:

- expenses incurred in connection with the preclinical and clinical development of our product candidates and research programs, including under agreements with third parties, such as consultants, contractors and contract research organizations, or CROs;
- the cost of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants, contractors and contract manufacturing organizations, or CMOs;
- payments made under third-party licensing agreements; and
- laboratory supplies and research materials.

Internal costs include:

- personnel-related expenses, consisting of employee salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;

- the cost to develop manufacturing capability at our San Diego facility for manufacturing of cell therapies for use in clinical trials;
- the cost of manufacturing clinical materials for use in our preclinical studies and clinical trials at our San Diego facility; and
- facilities, depreciation and other expenses, consisting of direct and allocated expenses for rent and maintenance of facilities and insurance.

We expense research and development costs as incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the volume of service that has been performed at each reporting date. Upfront payments and milestone payments made for the licensing of technology are related to clinical stage programs and expensed as research and development in the period in which they are incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses or other long-term assets. These amounts are expensed as the related goods are delivered or the services are performed.

At any one time, we are working on multiple research and development programs. We track external costs by the stage of program, clinical or preclinical. Our internal resources, employees and infrastructure are not directly tied to any one program and are typically deployed across multiple programs. As such, we do not track internal costs on a specific program basis.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to CRO activity and manufacturing expenses. We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future, including in connection with our ongoing Phase 1 trial of P-PSMA-101 for the treatment of patients with mCRPC, Phase 1 trial of P-BCMA-ALLO1 for the treatment of patients with relapsed/refractory multiple myeloma and Phase 1 trial of P-MUC1C-ALLO1 for the treatment of patients with solid tumor cancers and additional clinical programs expected to commence as we expand our pipeline of drug candidates. We cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. Our development costs may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the extent to which we establish additional licensing agreements; and
- whether we choose to partner any additional product candidates and the terms of such partnership.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the cost structure and timing associated with the development of respective product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials and preclinical studies.

### General and Administrative

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates, including P-PSMA-101, P-BCMA-ALLO1 and P-MUC1C-ALLO1, and begin to commercialize any approved products.

### Other Income (Expense)

#### Interest Expense

Interest expense consists of interest expense on outstanding borrowings under our loan agreement and amortization of debt discount and debt issuance costs.

#### Other Income (Expense), Net

Other income (expense), net consists of interest income and miscellaneous income and expense unrelated to our core operations. Interest income is comprised of interest earned on our available-for-sale securities.

### Results of Operations

#### Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		Change
	2021	2020	
Revenues:			
Collaboration revenue	\$ 31,238	\$ —	\$ 31,238
Total revenue	31,238	—	31,238
Operating expenses:			
Research and development	136,734	103,520	33,214
General and administrative	35,915	23,029	12,886
Total operating expenses	172,649	126,549	46,100
Loss from operations	(141,411)	(126,549)	(14,862)
Other income (expense):			
Interest expense	(3,358)	(3,506)	148
Other income, net	19,795	280	19,515
Net loss before income tax	(124,974)	(129,775)	4,801
Income tax expense	—	—	—
Net loss	\$ (124,974)	\$ (129,775)	\$ 4,801

#### Collaboration Revenue

Collaboration revenue of \$31.2 million for the year ended December 31, 2021, represents revenue recognized from the Takeda Collaboration Agreement consisting of \$30.2 million related to one-time performance obligations delivered upon the inception of the Takeda Collaboration Agreement in the fourth quarter of 2021 and \$1.0 million related to the research services we performed for Takeda in the fourth quarter of 2021 pursuant to the terms of the Takeda Collaboration Agreement.

#### Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2020 (in thousands):

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2021</u>	<u>2020</u>	
<b>External costs:</b>			
Clinical stage programs <sup>(1)</sup>	\$ 47,105	\$ 41,085	\$ 6,020
Preclinical stage programs and other unallocated expenses	32,356	24,386	7,970
<b>Internal costs:</b>			
Personnel	45,720	30,891	14,829
Facilities and other	11,553	7,158	4,395
<b>Total research and development expenses</b>	<b>\$ 136,734</b>	<b>\$ 103,520</b>	<b>\$ 33,214</b>

(1) Clinical stage programs include costs related to P-BCMA-101 and P-PSMA-101 for the year ended December 31, 2020 and costs related to P-BCMA-ALLO1, P-BCMA-101, and P-PSMA-101 for the year ended December 31, 2021.

Research and development expenses were \$136.7 million for the year ended December 31, 2021, compared to \$103.5 million for the year ended December 31, 2020. The increase in research and development expenses of \$33.2 million was primarily related to increases in the following: \$14.8 million of personnel expenses due to an increase in headcount combined with a \$4.2 million increase in stock-based compensation expense, \$8.0 million of external costs related to our preclinical programs due to an increased number of early stage programs, \$6.0 million of external costs related to our clinical stage programs including the ongoing enrollment and manufacturing for the P-BCMA-101 clinical trial and increased enrollment of the Phase 1 P-PSMA-101 trial, and \$4.4 million of internal costs related to facilities and other expenses primarily due to the increased activities in the pilot plant.

#### *General and Administrative Expenses*

General and administrative expenses were \$35.9 million for the year ended December 31, 2021, compared to \$23.0 million for the year ended December 31, 2020. The increase in general and administrative expenses of \$12.9 million was primarily related to an increase of \$9.5 million of personnel expenses due to an increase in headcount combined with a \$5.3 million increase in stock-based compensation expense, an increase of \$1.9 million in insurance costs, and an increase of \$1.5 million of professional fees.

#### *Interest Expense*

Interest expense was \$3.4 million for the year ended December 31, 2021, compared to \$3.5 million for the year ended December 31, 2020. Interest expense consisted of interest on the outstanding principal under our 2021 Amended Loan Agreement (as defined below) with Oxford Finance LLC, or Oxford, which was consistent during the respective periods.

#### *Other Income (Expense), Net*

Other income was \$19.8 million for the year ended December 31, 2021, compared to \$0.3 million for the year ended December 31, 2020. This increase in other income of \$19.5 million was primarily due to write off of deferred CIRM grant liability of \$19.8 million during the year ended December 31, 2021 related to an amount of grant awards that we no longer intend to repay as a result of our decision to wind down the P-BCMA-101 program and a loss on warrant liability of \$0.4 million recorded during the year ended December 31, 2020, partially offset by a \$0.6 million decrease in interest income during the year ended December 31, 2021 compared to 2020 driven by a decrease in the amount we invested in short-term investments combined with a decrease in available interest rates for investments.

#### **Liquidity and Capital Resources**

Since our inception in 2014, we have incurred significant operating losses. Our net losses were \$125.0 million and \$129.8 million for the years ended December 31, 2021 and 2020, respectively, and negative cash flows from operations of \$102.5 million and \$113.3 million, respectively. We expect to continue to incur net losses and negative cash flows from operations for at least the next several years. As of December 31, 2021, we had an accumulated deficit of \$406.9 million.

Our operations to date have focused on organizing and staffing our company, business planning, raising capital, in-licensing and acquiring intellectual property rights and establishing and protecting our intellectual property portfolio, developing our gene engineering technologies, identifying potential product candidates and undertaking research and development and manufacturing activities, including preclinical studies and clinical trials of our product candidates, and engaging in strategic transactions.

Our primary use of cash is to fund our operating expenses, which consist primarily of research and development expenditures including payroll and external costs associated with our preclinical and clinical stage programs, and to a lesser extent, general and

administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have funded our operations primarily through the sale of equity. Since our inception, we have raised \$224.0 million of gross proceeds from the sale of our common stock in our initial public offering in July 2020, raised an aggregate of \$334.3 million of gross proceeds from the sale of shares of our redeemable convertible preferred stock, received \$60.0 million of gross proceeds from borrowings under our loan agreement and received an aggregate of \$23.8 million in grant funding from CIRM. In the fourth quarter of 2021, we entered into a collaboration agreement with Takeda and received an upfront payment of \$45.0 million.

We expect that our cash and cash equivalents as of December 31, 2021 of \$206.3 million will be sufficient to fund our operations for at least the next twelve months from the date of issuance of the financial statements included in this Annual Report on Form 10-K. In the long term we will need additional financing to support our continuing operations and pursue our growth strategy.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for P-PSMA-101, P-BCMA-ALLO1 and P-MUC1C-ALLO1 or any other product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution activities. Accordingly, until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potential grants, collaborations, licenses or other similar arrangements. However, we may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. Especially in light of the COVID-19 pandemic, as well as recent or anticipated changes in interest rates and economic inflation, there can be no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

#### **Loan Agreement**

In 2017, we entered into a loan and security agreement with Oxford, as subsequently amended, pursuant to which we drew a Term A loan in the amount of \$20.0 million and a Term B loan, in the amount of \$10.0 million for a total outstanding balance of \$30.0 million as of December 31, 2021 and 2020. The Term A loan and Term B loan, or collectively Term Loans, bear interest at a floating per annum rate equal to 6.94% plus the greater of (a) the 30-day U.S. Dollar (USD) LIBOR rate and (b) 2.00%. As of December 31, 2021, the interest rate applicable to our Term Loans borrowing was 8.94%.

In June 2021, we entered into an amendment to the 2018 Loan Agreement, or the 2021 Amended Loan Agreement, with Oxford to extend the interest-only payment period and maturity date resulting in the interest-only payments period extend through June 30, 2023, followed by 30 equal monthly payments of principal and unpaid accrued interest and all outstanding Term Loans maturing on December 1, 2025. In conjunction with this amendment, we incurred a facility fee of \$1.1 million, which is due to Oxford on the maturity date. Our obligations under the 2021 Amended Loan Agreement are secured by a first priority security interest in substantially all of our current and future assets, except for our intellectual property. In addition, we have also agreed not to encumber our intellectual property assets, except as permitted by the 2021 Amended Loan Agreement. While any amounts are outstanding, we are subject to a number of affirmative and restrictive covenants, including covenants regarding dispositions of property, business combinations or acquisitions, among other customary covenants. We are also restricted from paying dividends or making other distributions or annual payments on our capital stock in excess of \$250,000, subject to limited exceptions. As of December 31, 2021, we were in compliance with all covenants under the 2021 Amended Loan Agreement.

In February 2022, we entered into a new Loan and Security Agreement, or the 2022 Loan Agreement, with Oxford. Pursuant to the terms of the 2022 Loan Agreement we borrowed \$60.0 million in term loans, a portion of which was used to repay the balance outstanding under the 2021 Amended Loan Agreement. Under the 2022 Loan Agreement the initial interest-only period is through April 1, 2025, followed by 23 equal monthly payments of principal and applicable interest. Upon the satisfaction of certain conditions set forth in the 2022 Loan Agreement, the interest-only period may be extended through April 1, 2026, followed by 11 equal monthly payments of principal and applicable interest. As a result, all amounts outstanding under the 2022 Loan Agreement will mature on February 1, 2027. In connection with the repayment of the balance outstanding under the 2021 Amended Loan Agreement, we incurred amendment and final payment fees of \$1.6 million previously due on the earlier of (i) the maturity date, (ii) acceleration of any Term Loan, or (iii) the prepayment of the Term Loans. We have an option to repay the outstanding debt under the 2022 Loan Agreement at any time in increments of \$5.0 million, subject to a prepayment fee of 1.0% if the term loans are prepaid on or prior to February 22, 2024, after which no prepayment penalty would be applied. Consistent with the 2021 Amended Loan Agreement, there is

a 7.5% final payment fee payable on the earlier of (i) the new maturity date, (ii) acceleration of the new loan, or (iii) the prepayment of the new loan.

On November 30, 2020, ICE Benchmark Administration, with the support of the United States Federal Reserve and the FCA, announced plans to consult on ceasing publication of USD LIBOR on December 31, 2021 for only the one week and two month USD LIBOR tenors, and on June 30, 2023 for all other USD LIBOR tenors. Various central bank committees and working groups continue to discuss replacement of benchmark rates, the process for amending existing LIBOR-based contracts, and the potential economic impacts of different alternatives. The Alternative Reference Rates Committee has identified the Secured Overnight Financing Rate, or SOFR, as its preferred alternative rate for USD LIBOR. SOFR is a measure of the cost of borrowing cash overnight, collateralized by U.S. Treasury securities, and is based on directly observable U.S. Treasury-backed repurchase transactions.

### Operating Lease Agreements

As of December 31, 2021, we had operating leases for manufacturing, laboratory and office space in San Diego, California consisting of approximately 87,000 square feet with remaining lease terms of 8.0 years. The manufacturing and laboratory and office space lease agreements include two options to extend the term for a period of 5 years each. Additionally, we had operating leases for dedicated manufacturing suites at our contract manufacturers with remaining lease terms of up to 2 years.

In October 2018, we entered into a lease agreement for a facility in San Diego, California to be used for research and development and administrative activities. The lease term commenced on April 1, 2019 and will expire on December 31, 2029. In October 2019, we entered into a lease amendment to expand the existing premises. The lease term for the additional premises commenced on July 29, 2020 and will expire on December 31, 2029.

In July 2019, we entered into a lease agreement for a facility in San Diego, California that was retrofitted to Good Manufacturing Practice standards and is used for manufacturing in our early-stage clinical trials. The lease term commenced on June 26, 2020 and will expire on December 31, 2029.

In October 2021, we entered into a sublease agreement for a facility in San Diego, California consisting of approximately 24,000 square feet to be used for research and administrative activities. The lease term will commence on or around May 1, 2022 and will expire on December 31, 2025.

### Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2021 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
Operating lease commitments	\$ 45,712	\$ 5,747	\$ 18,599	\$ 10,367	\$ 10,999
Debt obligations	40,896	2,719	38,177	—	—
<b>Total</b>	<b>\$ 86,608</b>	<b>\$ 8,466</b>	<b>\$ 56,776</b>	<b>\$ 10,367</b>	<b>\$ 10,999</b>

The debt obligation payments associated with the 2021 Amended Loan Agreement presented in the table above do not reflect the terms of the 2022 Loan Agreement, which we entered into in February 2022. In addition to the contractual obligations and commitments presented in the table above, a significant portion of our cash requirements is associated with personnel expense, including payroll, employment benefits, and hiring, employee retention and training costs. We expect that the amount of our personnel expense will increase in the foreseeable future as we continue to increase our headcount.

Furthermore, we enter into contracts in the normal course of business with contract research organizations, CMOs and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to one year after the date of cancellation. These payments are not included in the table above as the amount and timing of such payments are not known.

We have also entered into a several in-license agreements under which we are obligated to make aggregate milestone payments upon the achievement of specified preclinical, clinical and regulatory milestones as well as royalty payments. We have not included future payments under this agreement in the table above since the payment obligations under this agreement are contingent upon future events, such as our achievement of specified milestones or generating product sales. As of December 31, 2021, we were unable

to estimate the timing or likelihood of achieving these milestones or generating future product sales. See the subsection titled “—In-License Agreements” above.

### Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Cash used in operating activities	\$ (102,543)	\$ (113,328)
Cash provided by (used in) investing activities	222,384	(204,431)
Cash provided by financing activities	2,518	313,941
Net increase (decrease) in cash and cash equivalents	<u>\$ 122,359</u>	<u>\$ (3,818)</u>

During the year ended December 31, 2021, operating activities used \$102.5 million of cash, primarily resulting from our net loss of \$125.0 million, offset by non-cash items of \$2.3 million, and net cash provided by changes in our operating assets and liabilities of \$20.2 million. Non-cash charges consisted primarily of a \$19.8 million write off of the deferred CIRM grant liability, \$16.7 million in stock-based compensation, \$4.6 million in depreciation expense, and \$0.6 million of accretion of discount on issued term debt. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted primarily of a \$13.8 million increase in deferred revenue associated with the upfront payment received pursuant to the Takeda Collaboration Agreement, a \$7.8 million increase in accounts payable, a \$3.6 million decrease in operating lease right-of-use assets, and a \$2.0 million decrease in other long-term assets, offset in part by a \$3.1 million decrease in operating lease liabilities, a \$2.7 million increase in prepaid expenses and other current assets, and a \$1.2 million decrease in accrued liabilities.

During the year ended December 31, 2020, operating activities used \$113.3 million of cash, primarily resulting from our net loss of \$129.8 million, offset in part by non-cash expenses of \$10.8 million, and net cash provided by changes in our operating assets and liabilities of \$5.6 million. Non-cash charges consisted primarily of \$7.2 million in stock-based compensation, \$2.6 million in depreciation expense, \$0.8 million of accretion of discount on issued term debt, and \$0.4 million from change in fair value of the preferred stock warrant liability, offset in part by \$0.2 million in accretion of investment discount, net. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2020 consisted primarily of a \$10.3 million increase in accrued liabilities and a \$3.1 million decrease in operating lease right-of-use assets, offset in part by a \$4.2 million decrease in accounts payable, a \$3.3 million increase in prepaid expenses and other current assets, a \$0.2 million increase in other long-term assets, and a \$0.1 million decrease in operating lease liabilities.

#### Cash Provided by (Used in) Investing Activities

During the year ended December 31, 2021, net cash provided by investing activities was \$222.4 million, consisting of proceeds from maturities of short-term investments of \$225.0 million, partially offset by purchases of property and equipment of \$2.6 million.

During the year ended December 31, 2020, net cash used in investing activities was \$204.4 million, consisting of purchases of short-term investments of \$295.0 million and purchases of property and equipment of \$16.9 million, offset by proceeds from maturities of short-term investments of \$107.5 million. The purchase of short-term investments reflects the use of a higher cash balance from the proceeds of the IPO and Series D redeemable convertible preferred stock financing.

The timing of purchase and sales of our short-term investments is driven by our available cash balance and maturity of existing investments. The purchase of property and equipment for all periods related to equipment purchases as we expanded our research and development and manufacturing activities, in addition to corporate office space.

#### Cash Provided by Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was \$2.5 million, consisting of proceeds from the exercises of stock options and stock purchases under our employee stock compensation plans.

During the year ended December 31, 2020, net cash provided by financing activities was \$313.9 million, consisting primarily of \$205.7 million in net proceeds from our initial public offering, \$104.1 million in net proceeds from the sale of preferred stock and \$4.2 million in grant payments from CIRM.

## Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our financial statements, which are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses and other income during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to revenue, preclinical and clinical study accruals and stock-based compensation costs. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe the following accounting policies and estimates to be most critical to the preparation of our consolidated financial statements. We believe that the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

### Revenue Recognition

Our revenues to date have been generated primarily through collaboration and license agreements. Our collaboration and license agreements may contain multiple elements including intellectual property licenses and research, and development services. Consideration we receive under these arrangements may include upfront payments, research and development funding, cost reimbursements, research, development, regulatory and commercial milestone payments, and royalty payments.

We apply Accounting Standard Codification Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), issued by the Financial Accounting Standards Board ("FASB") to account for our contracts with customers. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that we expect to be entitled to receive in exchange for these services and excludes sales incentives and amounts collected on behalf of third parties. We analyze the nature of these performance obligations in the context of individual collaboration and license agreements in order to assess the distinct performance obligations. We evaluate our contracts with customers for proper classification in the consolidated statements of operations based on the nature of the underlying activity. Transactions with customers recorded in our consolidated statements of operations are recorded on either a gross or net basis, depending on the characteristics of the collaborative relationship.

To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

We use judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers. Determining whether a promised goods or service is a separate performance obligation requires the use of significant judgment. A change in such judgment could result in a significant change in the period in which revenue is recognized. We determine standalone selling price based on our overall pricing and discounting objectives, taking into consideration the type of services, estimates of hourly market rates, and stage of the research, development or clinical trials. The process for determining the transaction price involves significant judgment and includes consideration of multiple factors such as estimated revenues, market size, and development risk, among other factors contemplated in negotiating the arrangement with the customer. We determine the transaction price based on the consideration to which we expect to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from our customers. Our collaboration and license agreement contains no consideration payable to our customer or a significant financing component.

### Performance Obligations

The following is a description of principal goods and services from which we generate revenue.

#### *Intellectual property licenses*

We generate revenue from licensing our intellectual property including know-how and development and commercialization rights. These licenses provide customers with a term-based license to further research, develop and commercialize our internally-discovered platform technologies for specified therapeutic indications. The consideration we receive in the form of nonrefundable upfront consideration allocated to the functional intellectual property licenses is recognized at a point in time for licenses determined to be distinct from other performance obligations in the contract when we transfer such license to the customer. If the license is combined with other goods or services into one performance obligation, the revenue is recognized over a period of time based on our method of measuring progress in which we satisfy the combined performance obligation. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Our licensing agreements are generally cancelable. Customers have the right to terminate their contracts upon notice. We have the right to terminate the contracts generally only if the customer is in breach of the contract and fails to remedy the breach in accordance with the contractual terms.

#### *Material Rights*

Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right, (i.e., an optional good or service offered for free or at a discount) to the customer and if so, whether they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about the amount of the discount and likelihood that the option will be exercised. The exercise of a material right is accounted for as a contract modification for accounting purposes. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

#### *Research and development services*

We generate revenue from research and development services we provide to our customers in connection with the licensed intellectual property. The services we provide to our customers primarily include scientific research activities. Revenue associated with these services is recognized over time using the cost-to-cost input method, based on the total estimated costs to fulfill the obligations.

#### *Contracts with Multiple Performance Obligations*

Our collaboration and license agreements with customers may contain multiple promised goods or services. Based on the characteristics of the promised goods and services we analyze whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. We determine standalone selling price based on our overall pricing and discounting objectives, taking into consideration the type of services, estimates of hourly market rates, and stage of the development and clinical trials.

ASC 606 requires that we allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in ASC 606 as the price at which an entity would sell a promised good or service separately to a customer. If other observable transactions in which we have sold the same performance obligation separately are not available, we estimate the standalone selling price of each performance obligation. When standalone selling prices for our products or services are not directly observable, we determine the standalone selling prices using relevant information available and apply suitable estimation methods considering market conditions and entity-specific factors including, but not limited to, features and functionality of the underlying intellectual property licenses and the economic potential associated with ongoing research activities. Key assumptions to determine the standalone selling price may also include development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

#### *Accrued Research and Development Expenses*

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services, however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the 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, CMOs in connection with the process development and scale-up activities and the production of clinical trial materials and contract research organizations in connection with clinical trials.

We base the expense recorded related to contract research and manufacturing on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and contract research organizations that supply materials and conduct services. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense 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 reporting amounts that are too high or too low 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 stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model for options. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with service-based vesting conditions. Forfeitures are recognized as they occur.

The Black-Scholes option-pricing model requires the use of subjective assumptions to determine the fair value of stock-based awards and shares purchasable under the ESPP. These assumptions include:

- *Fair value of common stock*—Determined based on the quoted market price of our common stock
- *Expected term*—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.
- *Expected volatility*—Since we were a privately held company until July 2020 and do not have significant trading history for our common stock, the expected volatility is estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- *Expected dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

As of December 31, 2021, the unrecognized stock-based compensation expense related to employee stock options was \$42.8 million and is expected to be recognized as expense over a weighted-average period of approximately 2.9 years. The intrinsic value of all outstanding stock options as of December 31, 2021 was approximately \$2.9 million, of which approximately \$2.8 million related to vested options and approximately \$0.1 million related to unvested options.

### **JOBS Act**

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this the extended transition period under the JOBS Act until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2025.

### **Recent Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements included in this Annual Report.

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

As of December 31, 2021, we had cash and cash equivalents of \$206.3 million. Cash consists of deposits with financial institutions. Interest income is sensitive to changes in the general level of interest rates. However, due to the nature of these investments, a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

As of December 31, 2021, we had \$30.0 million of borrowings outstanding under the 2021 Loan Agreement bearing interest at a variable rate equal to 30-day LIBOR plus 6.94%, subject to a floor of 8.94%. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. LIBOR is currently scheduled to be phased out on June 30, 2023. We have amended the terms of our Term Loans to replace LIBOR with an alternate benchmark rate, which has yet to be established. The consequences of these developments cannot be entirely predicted, but could result in higher interest rates on the principal amount of the Term Loans.

***Foreign Currency Exchange Risk***

To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. Our expenses are generally denominated in U.S. dollars. However, we have contracted with a limited number of foreign vendors located in Europe and Canada and may contract with foreign vendors in the future. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. A hypothetical 10% change in exchange rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

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

The financial statements and supplemental data required by this item are set forth at the pages indicated in Part IV, Item 15 of this Annual Report on Form 10-K.

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

None.

**Item 9A. Controls and Procedures.*****Evaluation of Disclosure Controls and Procedures***

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation, the Principal Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2021.

***Management's Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, our management concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2021.

***Attestation Report of the Registered Public Accounting Firm***

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies".

***Changes in Internal Control Over Financial Reporting***

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

**Item 9B. Other Information.**

None.

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

Not applicable.

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

The information required by this item (other than as set forth below) is incorporated herein by reference to our Proxy Statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, under the sections headed “Proposal 1: Election of Directors,” “Information Regarding Director Nominees and Current Directors,” “Information Regarding the Board of Directors and Corporate Governance” and “Executive Officers.”

We have adopted a written code of business conduct and ethics that applies to all our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. A current copy of the code of business conduct and ethics is available on the Corporate Governance section of our website at [www.poseida.com](http://www.poseida.com). We intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to SEC rules.

**Item 11. Executive Compensation.**

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, under the section headed “Executive Compensation.”

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, under the section headed “Security Ownership of Certain Beneficial Owners and Management.”

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, under the sections headed “Transactions with Related Persons and Indemnification” and “Information Regarding the Board of Directors and Corporate Governance.”

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

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K, under the section headed “Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm.”

**Item 15. Exhibits, Financial Statement Schedules.**

We have filed the following financial statements and financial statement schedules as part of this Annual Report:

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<a href="#">Report of Independent Registered Public Accounting Firm</a>	126
<a href="#">Consolidated Balance Sheets as of December 31, 2021 and 2020</a>	127
<a href="#">Consolidated Statements of Operations and Comprehensive Loss for the Years ended December 31, 2021 and 2020</a>	128
<a href="#">Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years ended December 31, 2021 and 2020</a>	129
<a href="#">Consolidated Statements of Cash Flows for the Years ended December 31, 2021 and 2020</a>	130
<a href="#">Notes to Consolidated Financial Statements</a>	131

**Exhibits**

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

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

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Poseida Therapeutics, Inc. and its subsidiaries (the “Company”) as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of changes in convertible preferred stock and stockholders’ equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

**Change in Accounting Principle**

As discussed in Note 11 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2020.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Diego, California  
March 10, 2022

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

**Poseida Therapeutics, Inc.**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share amounts)

	December 31,	
	2021	2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 206,325	\$ 83,966
Short-term investments	—	225,186
Prepaid expenses and other current assets	7,548	4,844
Total current assets	213,873	313,996
Property and equipment, net	22,050	23,336
Operating lease right-of-use assets	26,177	24,986
Intangible assets, net	1,320	1,320
Goodwill	4,228	4,228
Other long-term assets	1,661	3,618
Total assets	\$ 269,309	\$ 371,484
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 8,961	\$ 763
Accrued expenses and other liabilities	23,540	24,454
Operating lease liabilities, current	6,337	4,808
Deferred revenue, current	4,497	—
Total current liabilities	43,335	30,025
Term debt	29,357	29,133
Deferred CIRM grant liability	3,992	23,755
Deferred revenue, non-current	9,265	—
Deferred tax liability	55	55
Operating lease liabilities, non-current	25,504	25,374
Other long-term liabilities	1,590	1,174
Total liabilities	113,098	109,516
<i>Commitments and Contingencies (Note 11)</i>		
Stockholders' equity:		
Common stock, \$0.0001 par value: 250,000,000 shares authorized at December 31, 2021, and 2020; 62,523,596 and 61,860,897 shares issued and outstanding as of December 31, 2021 and 2020, respectively	6	6
Additional paid-in capital	563,064	543,842
Accumulated other comprehensive income	—	5
Accumulated deficit	(406,859)	(281,885)
Total stockholders' equity	156,211	261,968
Total liabilities and stockholders' equity	\$ 269,309	\$ 371,484

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

**Poseida Therapeutics, Inc.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2021	2020
Revenues:		
Collaboration revenue	\$ 31,238	\$ —
Total revenue	31,238	—
Operating expenses:		
Research and development	\$ 136,734	\$ 103,520
General and administrative	35,915	23,029
Total operating expenses	172,649	126,549
Loss from operations	(141,411)	(126,549)
Other income (expense):		
Interest expense	(3,358)	(3,506)
Other income, net	19,795	280
Net loss before income tax	(124,974)	(129,775)
Income tax expense	—	—
Net loss	\$ (124,974)	\$ (129,775)
Other comprehensive income (expense):		
Unrealized loss on short-term investments	\$ (5)	\$ (14)
Comprehensive loss	\$ (124,979)	\$ (129,789)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.01)	\$ (3.61)
Weighted-average number of shares outstanding, basic and diluted	62,235,940	35,996,901

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

**Poseida Therapeutics, Inc.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**  
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2020	32,934,785	\$ 222,173	13,196,419	\$ 2	\$ 2,689	\$ 19	\$ (152,221)	\$ (149,511)
Transition adjustment from adoption of ASC 842 (Note 2)	—	—	—	—	—	—	111	111
Issuance of common stock under employee stock compensation plans	—	—	219,370	—	224	—	—	224
Issuance of Series D preferred stock for cash, net of issuance costs \$5,359	10,018,300	104,140	—	—	—	—	—	—
Issuance of common stock for conversion of preferred stock in closing of initial public offering	(42,953,085)	(326,313)	34,445,108	3	326,309	—	—	326,312
Issuance of common stock from initial public offering, net of issuance costs of \$18,018	—	—	14,000,000	1	205,742	—	—	205,743
Stock-based compensation expense	—	—	—	—	7,220	—	—	7,220
Reclassification of Series A-1 and Series B warrants	—	—	—	—	1,658	—	—	1,658
Unrealized loss on available-for-sale securities	—	—	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	—	—	(129,775)	(129,775)
Balance at December 31, 2020	—	\$ —	61,860,897	\$ 6	\$ 543,842	\$ 5	\$ (281,885)	\$ 261,968
Issuance of common stock under employee stock compensation plans	—	—	662,699	—	2,518	—	—	2,518
Stock-based compensation expense	—	—	—	—	16,704	—	—	16,704
Unrealized loss on available-for-sale securities	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(124,974)	(124,974)
Balance at December 31, 2021	—	\$ —	62,523,596	\$ 6	\$ 563,064	\$ —	\$ (406,859)	\$ 156,211

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

**Poseida Therapeutics, Inc.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,	
	2021	2020
<b>Operating Activities:</b>		
Net loss	\$ (124,974)	\$ (129,775)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	4,552	2,586
Stock-based compensation	16,704	7,220
Write off of deferred CIRM grant liability	(19,763)	—
Change in fair value of warrant liability	—	387
Accretion of discount on issued term debt	639	805
Amortization of premium and accretion of discounts on investments, net	133	(174)
Gain on disposal of property and equipment	(2)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,656)	(3,296)
Operating lease right-of-use assets	3,580	3,108
Other long-term assets	1,957	(207)
Accounts payable	7,842	(4,171)
Accrued liabilities	(1,204)	10,320
Operating lease liabilities	(3,113)	(131)
Deferred revenue	13,762	—
Net cash used in operating activities	<u>(102,543)</u>	<u>(113,328)</u>
<b>Investing Activities:</b>		
Purchases of property and equipment	(2,634)	(16,908)
Proceeds from disposal of property and equipment	18	—
Purchases of short-term investments	—	(295,023)
Proceeds from maturities of short-term investments	225,000	107,500
Net cash provided by (used in) investing activities	<u>222,384</u>	<u>(204,431)</u>
<b>Financing Activities:</b>		
Net proceeds from issuance of common stock under employee stock compensation plans	2,518	223
Issuance of Series D financing, net of issuance costs	—	104,141
Proceeds from initial public offering, net of issuance costs	—	205,743
Net proceeds from CIRM grant awards	—	4,163
Payment of debt issuance costs	—	(329)
Net cash provided by financing activities	<u>2,518</u>	<u>313,941</u>
Net increase (decrease) in cash and cash equivalents	122,359	(3,818)
Cash and cash equivalents at beginning of period	83,966	87,784
Cash and cash equivalents at end of period	<u>\$ 206,325</u>	<u>\$ 83,966</u>
<b>Non-cash operating, investing and financing activities:</b>		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 647	\$ 211
Tenant improvement receivable from landlord	—	137
Right-of-use assets obtained in exchange for operating lease liabilities	4,771	5,346
Conversion of redeemable convertible preferred stock to common stock upon closing of initial public offering	—	326,313
<b>Supplemental disclosure of cash flow information:</b>		
Interest paid	\$ 2,719	\$ 3,027

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

**Poseida Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**Note 1. Nature of Business and Basis of Presentation**

***Nature of Operations***

Poseida Therapeutics, Inc. (the “Company” or “Poseida”) is a clinical-stage biopharmaceutical company dedicated to utilizing its proprietary gene engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. The Company has discovered and is developing a broad portfolio of product candidates in a variety of indications based on its core proprietary platforms, including its non-viral piggyBac DNA Delivery System, Cas-CLOVER Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies.

The Company is subject to risks and uncertainties common to development-stage companies in the biotechnology industry, including, but not limited to, 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. Product candidates currently under development will require significant additional 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 and extensive compliance-reporting capabilities. Even if the Company’s therapeutic development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

***Liquidity and Capital Resources***

The Company has experienced net losses and negative cash flows from operations since its inception and has relied on its ability to fund its operations primarily through equity financings. For the years ended December 31, 2021 and 2020, the Company has incurred net losses of \$125.0 million and \$129.8 million respectively, and negative cash flows from operations for these same periods of \$102.5 million and \$113.3 million, respectively. The Company expects it will continue to incur net losses and negative cash flows from operations for at least the next several years. As of December 31, 2021 the Company had an accumulated deficit of \$406.9 million.

The Company expects that its cash and cash equivalents as of December 31, 2021 of \$206.3 million will be sufficient to fund its operations for at least the next twelve months from the date of issuance of these consolidated financial statements. In the long term the Company will need additional financing to support its continuing operations and pursue its business strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed would have a negative impact on the Company’s financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

***Basis of Preparation and Consolidation***

The consolidated financial statements reflect the Company’s financial position, results of operations and cash flows, in conformity with generally accepted accounting principles in the United States (“GAAP”) and include the accounts of Poseida Therapeutics, Inc. and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated.

These consolidated financial statements reflect a 1-for-1.247 reverse stock split of the Company’s common stock, which became effective on July 2, 2020. All share and per share data for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retrospectively, where applicable, to reflect the reverse stock split.

***Risk and Uncertainties***

In March 2020, the World Health Organization made the assessment that a novel strain of coronavirus, SARS-CoV-2, a novel strain of coronavirus, commonly referred to as COVID-19 had become a global pandemic. The impact of this pandemic has been and may continue to be extensive in many aspects of society, which has resulted in and may continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

Impacts to the Company’s business, some of which the Company has already experienced, include, but are not limited to, temporary closures of its facilities or those of its vendors, disruptions or restrictions on its employees’ ability to travel, disruptions to or delays in ongoing laboratory experiments, preclinical studies, clinical trials, third-party manufacturing supply and other operations,

the diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, interruptions or delays in the operations of the U.S. Food and Drug Administration (“FDA”) or other regulatory authorities, and the Company’s ability to raise capital and conduct business development activities.

## **Note 2. Summary of Significant Accounting Policies**

### ***Use of Estimates***

The preparation of consolidated financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates, which include, but are not limited to, estimates related to revenue, accrued expenses, stock-based compensation expense, deferred tax valuation allowances and, prior to the Company’s initial public offering (“IPO”) completed in July 2020, the fair value of common stock and warrant liability. The Company bases its estimates on historical experience and other market-specific or relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Prior to the IPO, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the 2004 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. Each valuation methodology includes estimates and assumptions that require the Company’s judgment. These estimates and assumptions include a number of objective and subjective factors, including the prices at which the Company sold shares of preferred stock and the superior rights, preferences and privileges of the preferred stock relative to the common stock; the Company’s stage of development and material risks related to its business; the progress of the Company’s research and development programs, including the status and results of preclinical studies for its product candidates and progress of its development of manufacturing processes; external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry; the Company’s results of operations and financial position, including its levels of available capital resources, outstanding debt and its historical and forecasted performance and operating results; the lack of an active public market for the Company’s common stock and preferred stock; the likelihood of achieving a liquidity event, such as an IPO or sale of the Company in light of prevailing market conditions; the hiring of key personnel; and the analysis of IPOs and the market performance of publicly traded companies in the biopharmaceutical industry, as well as recently completed mergers and acquisitions of peer companies. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

### ***Segment Information***

The Company’s sole operations consist of developing therapeutics for patients with high unmet medical need. Accordingly, the Company has determined that it operates in one operating and reportable business segment. Operating segments are defined as components of an enterprise about which separate financial information is evaluated regularly by the Company’s chief operating decision maker, who is its Chief Executive Officer, in deciding how to allocate resources and assess performance. The Company’s chief operating decision maker allocates resources and assesses performance based upon discrete financial information at the consolidated level. All of the Company’s tangible assets are held in the United States.

### ***Fair Value Measurements***

Certain financial instruments are required to be recorded at fair value. Other financial instruments, like cash are recorded at cost, which approximates fair value. Cash equivalents and short-term investments are comprised of available-for-sale securities, which are carried at fair value. Additionally, carrying amounts of accounts payable and accrued liabilities approximate fair value because of the short maturity of those instruments. The carrying value of the Company’s term debt approximates its fair value due to its variable interest rate, which approximates a market interest rate.

### ***Concentration of Business Risk***

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services. The Company’s revenue has been derived from a collaboration and license agreement with a single customer.

### ***Leases***

The Company accounts for leases in accordance with Accounting Standards Codification Topic 842, *Leases*, (“ASC 842”). The Company determines if an arrangement is a lease at contract inception. A lease exists when a contract conveys the right to control the

use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the Company has the right to control the use of the identified asset.

Operating leases where the Company is the lessee are included in lease receivables, operating lease right-of-use (“ROU”) assets, operating lease liabilities, current and operating lease liabilities, non-current on its consolidated balance sheets. The lease liabilities are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date.

ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. The rates implicit in the Company’s leases are not known, therefore, the incremental borrowing rate is used based on the information available at commencement date in determining the present value of lease payments. The Company’s incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

The lease term for all of the Company’s leases includes the noncancelable period of the lease. Where the Company’s lease term is impacted by options to extend or terminate the lease, when it is reasonably certain that it will exercise such option, then the lease payments are included in the measurement of the lease asset or liability.

The Company has elected not to recognize ROU assets and lease liabilities for all short-term leases that have a lease term of 12 months or less. The Company recognizes the lease payments associated with its short-term leases as an expense on a straight-line basis over the lease term. There are no variable lease payments associated with these leases. Additionally, the Company has elected to account for the lease and non-lease components together as a single lease component for its real estate asset class.

#### ***Deferred Offering Costs***

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. Deferred offering costs of \$18.3 million, incurred in connection with the Company’s July 2020 IPO, were net against the gross proceeds on the statement of stockholders’ equity (deficit) for the year ended December 31, 2020.

#### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and short-term investments. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. Deposits held at these institutions may exceed the amount of insurance provided on such deposits.

#### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments purchased with original final maturities of 90 days or less from the date of purchase to be cash equivalents. Cash and cash equivalents consist of deposits with financial institutions and marketable securities. Cash equivalents are reported at fair value. The Company utilizes a credit card that requires a cash collateral account to secure its outstanding balance. While cash in this account is not legally restricted, the availability of future credit is dependent upon maintenance of a compensating balance sufficient to cover outstanding balances. The balance held in this account as of both December 31, 2021 and 2020 was \$0.2 million. Amounts outstanding on the credit card and recorded as accounts payable were \$0.1 million as of both December 31, 2021 and 2020.

#### ***Short-Term Investments***

Investments with a remaining maturity when purchased of greater than three months are classified as short-term investments in the consolidated balance sheet and consist primarily of U.S. Treasury and other government agency obligations. As the Company’s entire investment portfolio is considered available for use in current operations, the Company classifies all investment as available-for-sale and as current assets. Debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders’ equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the instrument. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be “other than temporary,” the Company reduces the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

### Goodwill and Other Intangible Assets

Intangible assets were acquired as part of a business combination and have been capitalized at their acquisition date fair value. Indefinite-lived in process research and development (“IPR&D”) is not subject to amortization but is tested annually for impairment or more frequently if there are indicators of impairment. The Company tests its indefinite-lived IPR&D annually for impairment during the fourth quarter. In testing indefinite-lived IPR&D for impairment, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that its fair value is less than its carrying amount, or the Company can perform a quantitative impairment analysis to determine the fair value of the indefinite-lived IPR&D without performing a qualitative assessment. Qualitative factors that the Company considers include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If the Company chooses to first assess qualitative factors and it determines that it is more likely than not that the fair value of the indefinite-lived IPR&D is less than its carrying amount, the Company would then determine the fair value of the indefinite-lived IPR&D. Under either approach, if the fair value of the indefinite-lived IPR&D is less than its carrying amount, an impairment charge would be recognized for the difference between the fair value and the carrying amount. There was no impairment of IPR&D for the years ended December 31, 2021 and 2020.

The Company additionally tests its goodwill for impairment annually during the fourth quarter, or whenever events or changes in circumstances indicate an impairment may have occurred. Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount of the asset or asset group over the estimated asset’s fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse results from developmental work, adverse changes in applicable laws or regulations and a variety of other circumstances. In evaluating the recoverability of the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. There were no impairments of goodwill for the years ended December 31, 2021 and 2020.

### Property and Equipment

Property and equipment are stated at cost and depreciated or amortized using the straight-line method, based on their estimated useful lives as follows:

Asset Classification	Estimated Useful Life (years)
Laboratory equipment	5
Leasehold improvements	Lesser of useful life or lease-term
Computer equipment and software	3
Furniture and fixtures	7

Maintenance and repair costs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the Company’s consolidated balance sheet and any resulting gain or loss is reflected in the Company’s consolidated statement of operations and comprehensive loss.

Property and equipment are reviewed annually for impairment or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net undiscounted cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There has been no impairment of long-lived assets during the years ended December 31, 2021 and 2020.

### Revenue Recognition

The Company’s revenues to date have been generated primarily through collaboration and license agreements. The Company’s collaboration and license agreements may contain multiple elements including intellectual property licenses and research, and development services. Consideration the Company receives under these arrangements may include upfront payments, research and development funding, cost reimbursements, research, development, regulatory and commercial milestone payments, and royalty payments.

The Company applies Accounting Standard Codification Topic 606, *Revenue from Contracts with Customers* (“ASC 606”), issued by the Financial Accounting Standards Board (“FASB”) to account for its contracts with customers. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that the Company expects to be entitled to receive in exchange for these services and excludes sales incentives and

amounts collected on behalf of third parties. The Company analyzes the nature of these performance obligations in the context of individual collaboration and license agreements in order to assess the distinct performance obligations. The Company evaluates its contracts with customers for proper classification in the consolidated statements of operations based on the nature of the underlying activity. Transactions with customers recorded in the Company's consolidated statements of operations are recorded on either a gross or net basis, depending on the characteristics of the collaborative relationship.

To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company uses judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers. Determining whether a promised goods or service is a separate performance obligation requires the use of significant judgment. A change in such judgment could result in a significant change in the period in which revenue is recognized. The Company determines standalone selling price based on its overall pricing and discounting objectives, taking into consideration the type of services, estimates of hourly market rates, and stage of the research, development or clinical trials. The process for determining the transaction price involves significant judgment and includes consideration of multiple factors such as estimated revenues, market size, and development risk, among other factors contemplated in negotiating the arrangement with the customer. The Company determines the transaction price based on the consideration to which it expects to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from our customers. The Company's collaboration and license agreement contains no consideration payable to our customer or a significant financing component.

### ***Performance Obligations***

The following is a description of principal goods and services from which the Company generates revenue.

#### *Intellectual property licenses*

The Company generates revenue from licensing its intellectual property including know-how and development and commercialization rights. These licenses provide customers with a term-based license to further research, develop and commercialize the Company's internally-discovered platform technologies for specified therapeutic indications. The consideration the Company receives in the form of nonrefundable upfront consideration allocated to the functional intellectual property licenses is recognized at a point in time for licenses determined to be distinct from other performance obligations in the contract when the Company transfers such license to the customer. If the license is combined with other goods or services into one performance obligation, the revenue is recognized over a period of time based on the Company's method of measuring progress in which it satisfies the combined performance obligation. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The Company's licensing agreements are generally cancelable. Customers have the right to terminate their contracts upon notice. The Company has the right to terminate the contracts generally only if the customer is in breach of the contract and fails to remedy the breach in accordance with the contractual terms.

#### *Material Rights*

Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer and if so, whether they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying license relative to the option exercise price, including assumptions about the amount of the discount and likelihood that the option will be exercised. The exercise of a material right is accounted for as a contract modification for accounting purposes. Amounts allocated to any material right are recognized as revenue when or as the related future goods or services are transferred or when the option expires.

#### *Research and development services*

The Company generates revenue from research and development services it provides to its customers in connection with the licensed intellectual property. The services the Company provides to its customers primarily include scientific research activities.

Revenue associated with these services is recognized over time using the cost-to-cost input method, based on the total estimated costs to fulfill the obligations.

#### ***Contracts with Multiple Performance Obligations***

The Company's collaboration and license agreements with customers may contain multiple promised goods or services. Based on the characteristics of the promised goods and services the Company analyzes whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The Company determines standalone selling price based on its overall pricing and discounting objectives, taking into consideration the type of services, estimates of hourly market rates, and stage of the development and clinical trials.

ASC 606 requires the Company to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in ASC 606 as the price at which an entity would sell a promised good or service separately to a customer. If other observable transactions in which the Company has sold the same performance obligation separately are not available, the Company estimates the standalone selling price of each performance obligation. When standalone selling prices for the Company's products or services are not directly observable, the Company determines the standalone selling prices using relevant information available and apply suitable estimation methods considering market conditions and entity-specific factors including, but not limited to, features and functionality of the underlying intellectual property licenses and the economic potential associated with ongoing research activities. Key assumptions to determine the standalone selling price may also include development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

#### ***Variable Consideration***

The Company's contracts with customers generally include two types of variable consideration: (i) research, development and regulatory milestone payments, which the Company is entitled to upon achievement of such specific milestones and (ii) one-time sales-based payments and sales-based royalties associated with licensed intellectual property.

If an arrangement includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control are generally not considered probable of being achieved until those approvals are received.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. The Company recognizes revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

Under the royalty exception in ASC 606 for licensed intellectual property the Company does not recognize any revenue for the variable amounts related to sales-based royalties and milestones until the later of when the sales occur, or the performance obligation is satisfied or partially satisfied. Accordingly, the revenue related to future sales-based royalties and milestones are excluded from the estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied.

#### ***Disaggregation of Revenue***

The Company operates in one reportable business segment and has one customer.

#### ***Contract Assets and Contract Liabilities***

The Company receives payments from customers based on contractual terms. Accounts receivable are recorded when the right to consideration becomes unconditional. For research and development services, the Company generally bills its customers monthly or quarterly as the services are performed. Payment terms on invoiced amounts are typically 30 - 60 days. Contract assets include amounts related to the Company's contractual right to consideration for both completed and partially completed performance obligations that have not been invoiced and for which the Company does not yet have the right to payment. The current portion of contract asset is included in prepaid expenses and other current assets in the consolidated balance sheet. The non-current portion of contract assets is included in other non-current assets in the consolidated balance sheet. Contract liabilities consist of deferred revenue and include payments received in advance of performance under the contract.

#### ***Cost to Obtain and Fulfill a Contract***

The Company generally does not incur costs to obtain new contracts. Costs to fulfill contracts are expensed as incurred.

### **Research and Development**

Research and development expense consists of labor, material, equipment, and allocated facilities costs of the Company's scientific staff who are working on research and development projects. Research and development costs are charged to operations as incurred.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses or other long-term assets. The advanced payments are expensed as the related goods are delivered or the services are performed.

### **Research and Manufacturing Contract Costs and Accruals**

The Company has entered into various research and development and manufacturing agreements. These agreements are generally cancelable, and related payments are recorded as the corresponding expenses are incurred. The Company records accruals for estimated costs incurred to date. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the research studies or clinical trials and manufacturing activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

### **Patent Costs**

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

### **Stock-Based Compensation**

Stock-based compensation related to stock options granted to the Company's employees and consultants and the 2020 Employee Stock Purchase Plan ("ESPP") awards is measured at the grant date based on the fair value of the award. The fair value is recognized as stock-based compensation expense in the consolidated financial statements over the requisite service period, which is generally the vesting period of the respective awards. Compensation related to service-based awards is recognized starting on the grant date on a straight-line basis over the vesting period, which is typically two to four years. The Company recognizes the fair value of stock options granted to non-employees as stock-based compensation expense over the period in which the related services are received. Stock-based compensation expense related to stock options granted to non-employees is recognized based on the grant date fair value of awards as the stock options are earned. The Company believes that the estimated fair value of stock options is more readily measurable than the fair value of the services rendered. All option grants require continued service to continue vesting. For the ESPP, the requisite service period is generally the period of time from the offering date to the purchase date. The Company accounts for the forfeitures in the period in which they occur.

The Company uses the Black-Scholes valuation model to estimate the grant date fair value of the stock option awards and shares purchasable under the ESPP. The determination of the fair value of each stock award using the option-pricing model is affected by the Company's assumptions regarding a number of variables including the fair value of the common stock at the date of grant, the expected term of the awards, the expected stock price volatility over the term of the awards, risk-free interest rate, and dividend rate. The Company's assumptions with respect to these variables are as follows:

- **Fair Value of Common Stock**—Prior to the IPO, the Company's common stock was not publicly traded, therefore the Company estimated the fair value of its common stock. Following the IPO, the fair value of the Company's common stock for awards with service-based vesting is the closing selling price per share of its common stock as reported on the Nasdaq Global Select Market on the date of grant or other relevant determination date.
- **Expected Term**—The expected term represents the period that the stock-based awards are expected to be outstanding. The Company determines the expected term using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For stock options granted to non-employees, the expected term equals the remaining contractual term of the option from the vesting date. For the ESPP, the expected term is the period of time from the offering date to the purchase date.
- **Expected Volatility**—Given the limited period of time the Company's stock has been traded in an active market, the expected volatility is estimated by taking the average historical price volatility for industry peers, consisting of several public companies in the Company's industry that are similar in size, stage, or financial leverage, over a period of time commensurate with to the expected term of the awards.

- Risk-Free Interest Rate—The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.
- Dividend Rate—The dividend yield assumption is zero, as the Company has no plans to make dividend payments in the foreseeable future.

### **Comprehensive Loss**

Comprehensive loss includes net loss as well as other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on available-for-sale securities.

### **Net Income (Loss) Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per common share, since the effects of potentially dilutive securities are anti-dilutive due to the net loss position of all periods presented.

### **Income Taxes**

Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts of assets and liabilities and their respective tax bases, as well as net operating losses and credit carry forwards applied by the enacted tax rates expected to be in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

### **Emerging Growth Company Status**

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

### **Recently Adopted Accounting Pronouncements**

In January 2017, the FASB issued ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. The new standard simplified the measurement of goodwill by eliminating step two of the two-step impairment test. Step two measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount of that goodwill. The new guidance requires an entity to compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. Additionally, an entity is required to consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The Company adopted this standard on January 1, 2021. The adoption of this standard had no impact on the Company’s consolidated financial statements and disclosures.

In December 2019, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (“ASU 2019-12”), which is intended to simplify the

accounting for income taxes. ASU 2019-12 removed certain exceptions to the general principles in Topic 740 and also clarified and amended existing guidance to improve consistent application. The Company adopted this standard on January 1, 2021. The adoption of this standard had no impact on the Company's consolidated financial statements and disclosures.

### Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses*, to improve financial reporting by requiring timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. The ASU requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. This guidance will become effective for the Company beginning January 1, 2023, with early adoption permitted. The Company is currently evaluating the potential impact the adoption of ASU 2016-13 may have on its financial position and results of operations.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation- Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815- 40)* which provides guidance on modifications or exchanges of a freestanding equity-classified written call option that is not within the scope of another Topic. An entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as an exchange of the original instrument for a new instrument ASU 2021-04 also provides further guidance on measuring the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. ASU 2021-04 also provides guidance on the recognition of the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange on the basis of the substance of the transaction, in the same manner as if cash had been paid as consideration. This guidance will become effective for the Company beginning January 1, 2022. The Company is currently evaluating the potential impact the adoption of ASU 2021-04 may have on its financial position and results of operations.

### Note 3. Composition of Certain Balance Sheet Components

#### Prepaid expenses and other current assets

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

	December 31,	
	2021	2020
Contract research services	\$ 2,739	\$ 651
Prepaid insurance	2,355	2,226
Prepaid rent	354	217
Landlord reimbursement	—	137
Other	2,100	1,613
Total prepaid expenses and other current assets	<u>\$ 7,548</u>	<u>\$ 4,844</u>

#### Property and equipment, net

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

	December 31,	
	2021	2020
Laboratory equipment	\$ 14,192	\$ 11,420
Leasehold improvements	13,910	13,826
Computer equipment and software	2,137	1,381
Furniture and fixtures	928	928
Construction in progress	20	376
Total property and equipment	31,187	27,931
Less: Accumulated depreciation and amortization	(9,137)	(4,595)
Total property and equipment, net	<u>\$ 22,050</u>	<u>\$ 23,336</u>

Depreciation expense associated with property and equipment was \$4.6 million and \$2.6 million for the years ended December 31, 2021 and 2020, respectively.

**Goodwill and other intangible assets, net**

Goodwill and other intangible assets, net consist of the following as of (in thousands):

	December 31,	
	2021	2020
Goodwill	\$ 4,228	\$ 4,228
Indefinite lived intangible assets:		
IPR&D	\$ 1,320	\$ 1,320
Total intangible assets, net	<u>\$ 1,320</u>	<u>\$ 1,320</u>

There were no impairments of goodwill and other intangible assets for the years ended December 31, 2021 and 2020.

**Accrued and other liabilities**

Accrued and other liabilities consisted of the following as of (in thousands):

	December 31,	
	2021	2020
Contract research services	\$ 12,292	\$ 15,822
Payroll and related expense	8,760	6,793
Other	2,488	1,839
Total accrued expenses and other liabilities	<u>\$ 23,540</u>	<u>\$ 24,454</u>

**Note 4. Financial Instruments**

The following table summarizes the amortized cost and fair value of available-for-sale securities at December 31, 2021 and 2020 (in thousands):

	Amortized Cost/Cost	Unrealized Gains	Unrealized Losses	Fair Value
<b>At December 31, 2021:</b>				
Money market fund	\$ 176,102	\$ —	\$ —	\$ 176,102
Total	<u>\$ 176,102</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 176,102</u>
<b>At December 31, 2020:</b>				
Money market fund	\$ 70,713	\$ —	\$ —	\$ 70,713
U.S. government agency securities and treasuries	225,181	5	—	225,186
Total	<u>\$ 295,894</u>	<u>\$ 5</u>	<u>\$ —</u>	<u>\$ 295,899</u>

No available-for-sale debt securities held as of December 31, 2021 and 2020 had remaining maturities greater than one year. Unrealized gains and losses on available-for-sale securities are included as a component of comprehensive loss. At December 31, 2021, the Company did not have any securities in material unrealized loss positions.

The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The Company does not generally sell any investments prior to recovery of their amortized cost basis for any investments in an unrealized loss position.

**Note 5. Fair Value Measurement**

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 as of the measurement date. Applicable accounting guidance provides an established hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's

assumptions about the factors that market participants would use in valuing the asset or liability. There are three levels of inputs that may be used to measure fair value:

- Level 1 — Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities
- Level 2 — Significant other observable inputs other than Level 1 prices such as quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability
- Level 3 — Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity)

The Company classifies its money market funds and U.S. treasury securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The following table summarizes the Company's valuation hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as follows (in thousands):

	Level 1	Level 2	Level 3
<b>At December 31, 2021:</b>			
Assets			
Money market funds(1)	\$ 176,102	\$ —	\$ —
Short-term investments	—	—	—
<b>Total</b>	<b>\$ 176,102</b>	<b>\$ —</b>	<b>\$ —</b>
<b>At December 31, 2020:</b>			
Assets:			
Money market funds(1)	\$ 70,713	\$ —	\$ —
Short-term investments	225,186	—	—
<b>Total</b>	<b>\$ 295,899</b>	<b>\$ —</b>	<b>\$ —</b>

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheet.

#### Warrant liability

Prior to the IPO, the Company had 42,953,085 shares of outstanding convertible preferred stock and outstanding warrants to purchase an aggregate of 151,042 shares of convertible preferred stock. The fair value of these warrants was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates to value the preferred stock warrants. For the year ended December 31, 2020, the change in fair value of warrant liability was recorded as a loss of \$0.4 million included in other income, net in the Company's consolidated statement of operations and comprehensive loss.

At the closing of the IPO in July 2020, 42,953,085 shares of outstanding convertible preferred stock were automatically converted into 34,445,108 shares of common stock, and outstanding warrants to purchase an aggregate of 151,042 shares of convertible preferred stock became exercisable for 121,122 shares of common stock and were reclassified into permanent equity. Upon conversion, the Company reclassified the balance of warrant liability of \$1.7 million to additional paid in capital.

#### Note 6. Collaborations and License Agreement with Takeda

In October 2021, the Company entered into a collaboration and license agreement (the "Takeda Collaboration Agreement") with Takeda Pharmaceuticals USA, Inc. ("Takeda"), pursuant to which the Company granted to Takeda a worldwide exclusive license under the Company's certain platform technologies including piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms to research, develop, manufacture and commercialize gene therapy products for certain indications, including Hemophilia A. The parties are collaborating to initially develop up to six *in vivo* gene therapy programs and Takeda also has an option to add two additional programs to the collaboration. The Company is obligated to perform research activities to the extent requested by Takeda up to the candidate selection stage, after which Takeda is obligated to assume responsibility for further development, manufacturing and commercialization of each program.

Under the Takeda Collaboration Agreement, the Company received an upfront payment of \$45.0 million, of which \$5.0 million represents prepaid research funding. Takeda is obligated to provide funding for all collaboration program development costs; provided

that the Company is obligated to perform certain platform development activities at its own cost. Under the Takeda Collaboration Agreement, the Company is eligible to receive preclinical milestone payments that could potentially exceed \$82.5 million in the aggregate if preclinical milestones for all six programs are achieved. The Company is also eligible to receive future clinical development, regulatory and commercial milestone payments of \$435.0 million in the aggregate per target, with a total potential deal value over the course of the collaboration of up to \$2.7 billion, if milestones for all six programs are achieved and up to \$3.6 billion if the milestones related to the two optional programs are also achieved. The Company is entitled to receive tiered royalty payments on net sales in the mid-single to low double digits, subject to certain standard reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the latest of the expiration of the licensed patents covering such product in such country, ten years from first commercial sale of such product in such country, or expiration of regulatory exclusivity for such product in such country.

The promised goods and services under the Takeda Collaboration Agreement were accounted for as following separate performance obligations: (i) development and commercialization licenses for initial two indications, (ii) separate material rights associated with four additional licenses Takeda has an option to acquire individually, (iii) platform technology enhancement services, and (iv) research and development services.

In order to determine the transaction price, the Company evaluated all the payments to be received during the duration of the Takeda Collaboration Agreement. Certain milestones and additional fees were considered variable consideration, which were not included in the initial transaction price based on the most likely amount method. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The Company determined that the transaction price at the inception of the Takeda Collaboration Agreement consists of the upfront payment of \$40.0 million and \$5.0 million in prepaid research funding.

The Company allocated the transaction price to individual performance obligations on their relative standalone selling price basis. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services.

The performance obligation associated with the development and commercialization licenses for initial two indications was satisfied at the inception of the Takeda Collaboration Agreement. The separate material rights associated with additional licenses Takeda has an option to acquire individually are satisfied at a point in time in the future upon the earliest of Takeda exercising the option to acquire additional licenses or the expiration of the option. The platform technology enhancement services and the research and development services are satisfied over time as the Company performs the services for Takeda. The Company determined that the cost-based input method most faithfully depicts the pattern in which these performance obligations are satisfied. The Company recognizes revenue based on actual costs incurred as a percentage of total estimated costs as the Company completes its performance obligation under the Takeda Collaboration Agreement. Costs consist primarily of internal full-time employee (FTE) and certain reimbursable costs.

The Company recognized revenue for the combined performance obligation consisting of a development and commercialization license and platform technology enhancement services based on the amount of incurred development expenses reimbursed by the customer as a percentage of total expected reimbursable expenses associated with the contract. As of December 31, 2021, all future potential milestone payments were excluded from the estimated total transaction price as they were considered constrained.

For the year ended December 31, 2021, the Company recognized revenue of \$31.2 million from the Takeda Collaboration Agreement, consisting of \$30.2 million recognized at a point in time related to the development and commercialization licenses for the initial two indications, and \$1.0 million recognized for the platform technology enhancement services and the research and development services, which are delivered over time. As of December 31, 2021, the balance of estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied, or partially unsatisfied, pursuant to the Company's existing collaboration and license agreement consisted of \$4.5 million presented as a deferred revenue, current and \$9.3 million presented as a deferred revenue, non-current, in the accompanying consolidated balance sheet.

#### **Note 7. California Institute of Regenerative Medicine Awards**

The Company has been awarded funding from California Institute of Regenerative Medicine ("CIRM") to develop internal programs. Under the terms of the funding, both CIRM and the Company have co-funded specified programs, under which funding is provided in developmental milestones determined as a part of the award. The Company is obligated to share potential future revenues for the related programs with CIRM. The percentage of revenues due to CIRM in the future is dependent on the amount of the award received and whether revenue is from product sales or through license fees. The maximum revenue sharing amount the Company may be required to pay to CIRM is equal to nine times the total amount awarded and paid to the Company. The Company has the option to decline any and all amounts awarded by CIRM. As an alternative to revenue sharing, the Company has the option to convert the award

to a loan, which such option the Company must exercise on or before ten business days after the FDA notifies the Company that it has accepted the Company's application for marketing authorization. In the event the Company exercises its right to convert any award to a loan, it would be obligated to repay the loan within ten business days of making such election. Repayment amounts due to CIRM vary dependent on when the award is converted to a loan, ranging from 60% of the award granted to the full amount received plus interest at the rate of the three-month LIBOR rate plus 10% per annum. Since the Company may be required to repay some or all of the amounts awarded by CIRM, the Company accounts for these awards as a liability rather than revenue if the Company's intention is to convert the awards into a loan. Given the uncertainty in amounts due upon repayment, the Company has recorded amounts received without any discount or interest recorded, upon determination of amounts that would become due, the Company will adjust accordingly.

In December 2017, the Company was granted an award in the amount of \$19.8 million from CIRM to support the Company's P-BCMA-101 Phase 1 clinical trial. The award is paid based on developmental milestones, of which \$19.7 million had been received as of December 31, 2021 with up to an aggregate of \$0.1 million in future milestone payments. In the fourth quarter of 2021, the Company made the decision to wind down clinical development of the P-BCMA-101 program, which resulted in write off of the amount previously included in the deferred CIRM grant liability as the Company no longer intends to repay the award and is included in other income in the accompanying consolidated statement of operations.

In September 2018, the Company was granted an award in the amount of \$4.0 million from CIRM to support the Company's preclinical studies for its P-PSMA-101 program. The award is paid based on developmental milestones, of which the full \$4.0 million had been received as of December 31, 2021.

#### **Note 8. Term Debt**

In 2017, the Company entered into a loan and security agreement with Oxford Finance LLC ("Oxford"), as amended, pursuant to which the Company borrowed \$20.0 million under a Term A loan and \$10.0 million under a Term B loan (collectively with the Term A Loan, the "Term Loans") for a total outstanding balance of \$30.0 million as of December 31, 2021 and 2020.

In June 2021, the Company entered into an amendment to the Amended Loan Agreement ("2021 Amended Loan Agreement") with Oxford. Pursuant to the terms of the 2021 Amended Loan Agreement, the interest-only period on the Term Loans and the final maturity date were extended by 18 months. As a result, all amounts outstanding under the Term Loans will mature on December 1, 2025 (the "Maturity Date") and have interest-only payments through June 30, 2023, followed by 30 equal monthly payments of principal and unpaid accrued interest. The 2021 Amended Loan Agreement also included a facility fee of \$1.1 million due on the earlier of (i) the Maturity Date, (ii) acceleration of any Term Loan, or (iii) the prepayment of the Term Loans. All other terms under the Amended Loan Agreement remained unchanged. The Company accounted for this amendment as debt modifications in accordance with ASC Topic 470, *Debt* because the modification was not considered substantial.

The Term Loans bear interest at a floating per annum rate equal to (i) 6.94% plus (ii) the greater of (a) the 30-day U.S. Dollar LIBOR rate and (b) 2.0%. The interest rate for the Term Loans as of December 31, 2021 was 8.94% per annum. The Company is required to make a final payment of 7.5% of the principal balance outstanding, payable on the earlier of (i) the Maturity Date, (ii) acceleration of any Term Loan, or (iii) the prepayment of the Term Loans. In connection with the Term A Loan and the Term B Loan, the Company incurred debt issuance costs of \$1.0 million and \$0.3 million, respectively, which have been recorded as a debt discount and are being accreted to interest expense over the term of the Term A Loan and the Term B Loan, respectively. Interest on the Term A Loan and the Term B Loan, consisting of the stated interest rate, final payment fee and amortization of the discount, is being recognized under the effective interest method using a rate of 10.86% and 10.72%, respectively. As of December 31, 2021, the balance of the unamortized debt discount was \$0.6 million. The balance of the accrued final payment fee was \$1.6 million as of December 31, 2021 and is presented as other long-term liability in the accompanying consolidated balance sheet.

The Company has an option to prepay all, but not less than all, the Term Loans borrowed, provided that the Company will be obligated to pay a prepayment fee equal to 1.0% of the Term Loans prepaid. As disclosed in Note 15, subsequent to December 31, 2021, the Company repaid all balances outstanding under the Term Loans and entered into a new loan agreement with Oxford.

The Company may use the proceeds from the Term Loans solely for its working capital requirements and to fund its general business operations. The Company's obligations under the 2021 Amended Loan Agreement are secured by a first priority security interest in substantially all of its current and future assets, other than its intellectual property. In addition, the Company has also agreed not to encumber its intellectual property assets, except as permitted by the 2021 Amended Loan Agreement. While any amounts are outstanding under the 2021 Amended Loan Agreement, the Company is subject to a number of affirmative and restrictive covenants, including covenants regarding dispositions of property, business combinations or acquisitions, among other customary covenants. The Company is also restricted from declaring dividends or making other distributions or payments on its capital stock in excess of \$0.3 million per calendar year, subject to limited exceptions. As of December 31, 2021, the Company was in compliance with all covenants under the 2021 Amended Loan Agreement.

Pursuant to the loan and security agreement-with Oxford, in 2017, the Company issued to Oxford warrants to purchase an aggregate of up to 116,618 shares of the Company's Series A-1 Preferred Stock ("Series A-1 Warrants") at an exercise price of \$3.43 per share. The Company determined the fair value of the Series A-1 Warrants on the date of issuance was \$0.3 million. Upon the closing of the IPO, the Series A-1 Warrants became exercisable for 93,518 shares of common stock at an exercise price of \$4.28 per share. The fair value of the warrant liability at the date of the IPO was reclassified to additional paid-in-capital.

Also pursuant to the loan and security agreement-with Oxford, in 2018, the Company issued to Oxford warrants to purchase an aggregate of up to 17,212 shares of the Company's Series B Preferred Stock with an exercise price of \$5.81 per share ("2018 Series B Warrants") and in 2019, in conjunction with drawing the additional \$10.0 million in principal, the Company issued to Oxford warrants to purchase an aggregate of up to an additional 17,212 shares of the Company's Series B Preferred Stock, with an exercise price of \$5.81 per share ("2019 Series B Warrants"). The Company determined the fair value of the 2018 Series B Warrants and the 2019 Series B Warrants on the date of issuance was \$0.1 million and \$0.2 million, respectively. Upon the closing of the IPO, the Series B Warrants became exercisable for 27,604 shares of common stock at an exercise price of \$7.25 per share.

The fair value of the warrant liability at the date of the IPO was reclassified to additional paid-in-capital. The warrants will expire ten years from the date of the grant unless earlier exercised. The fair value of the warrants was originally treated as a debt discount and recorded as a preferred stock warrant liability. The debt discount is amortized over the term of the Term Loans to interest expense.

## **Note 9. Stockholders' Equity**

### ***Authorized Shares***

In connection with the completion of the Company's IPO in July 2020, the Company amended its certificate of incorporation to authorize 250,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of undesignated preferred stock, par value \$0.0001 per share, that may be issued from time to time by the Company's board of directors in one or more series. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Company's board of directors. Since the Company's inception, there have been no dividends declared.

### ***Public Offering and Related Transaction***

In July 2020, the Company completed its IPO selling 14,000,000 shares of its common stock at a public offering price of \$16.00 per share. Proceeds from the Company's IPO, net of underwriting discounts and other offering costs, were \$205.7 million. In connection with the IPO, all 42,953,085 shares of outstanding convertible preferred stock were automatically converted into 34,445,108 shares of the Company's common stock. Additionally, the outstanding warrants to purchase an aggregate of 151,042 shares of convertible preferred stock became exercisable for 121,122 shares of common stock and were reclassified into permanent equity.

### ***Convertible Preferred Stock***

Prior to its conversion to common stock, the Company's convertible preferred stock was classified as temporary equity on the Company's balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of the Company's control, including liquidation, sale or transfer of control of the Company. The Company had determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

In June 2020, the Company issued and sold 10,018,300 shares of Series D Preferred Stock, at a price of \$10.93 per share, for aggregate gross proceeds of \$109.5 million.

Convertible preferred stock immediately prior to the closing of the IPO consisted of the following (in thousands, except share amounts):

	July 14, 2020				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	9,696,798	9,696,798	\$ 31,063	\$ 31,063	7,776,095
Series A-1 Preferred Stock	3,370,263	3,253,645	11,083	11,083	2,609,176
Series B Preferred Stock	5,283,992	5,249,568	30,314	30,314	4,209,754
Series C Preferred Stock	14,734,774	14,734,774	149,713	149,713	11,816,169
Series D Preferred Stock	13,723,696	10,018,300	104,140	104,140	8,033,914
Total	<u>46,809,523</u>	<u>42,953,085</u>	<u>\$ 326,313</u>	<u>\$ 326,313</u>	<u>34,445,108</u>

#### Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Company's board of directors. Since the Company's inception, there have been no dividends declared.

#### Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2021:

Stock options issued and outstanding	9,899,707
Authorized for future options and award grants	3,752,093
Authorized for future issuance under Employee Stock Purchase Plan	<u>1,154,241</u>
Total	<u>14,806,041</u>

#### Note 10. Stock-Based Compensation

In July 2020, the Company's board of directors and stockholders approved and adopted the 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan became effective as of the completion of the IPO. Under the 2020 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other stock or cash-based awards to individuals who are employees, officers, directors or consultants of the Company. A total of 11,183,476 shares of common stock were approved to be initially reserved for issuance under the 2020 Plan. The number of shares that remained available for issuance under the Company's previous equity incentive plan as of the effective date of the 2020 Plan and shares subject to outstanding awards under the Company's previous equity incentive plan as of the effective date of the 2020 Plan that are subsequently canceled, forfeited or repurchased by the Company are added to the shares reserved under the 2020 Plan. The number of shares of common stock available for issuance under the 2020 Plan is automatically increased on the first day of each calendar year during the ten-year term of the 2020 Plan, beginning with January 1, 2021 and ending with January 1, 2030, by an amount equal to 5% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year or such lesser amount as determined by the Company's board of directors. The number of stock options and exercise prices were adjusted retrospectively for the Company's reverse stock split, which became effective in July 2020.

As of December 31, 2021, there were 3,752,093 shares available for future option grants or direct issuance under the 2020 Plan. Through December 31, 2021, the Company has exclusively granted stock options under the 2020 Plan. Shares issued under the 2020 Plan are newly issued shares and the Company has no intention to repurchase previously issued shares. The exercise price of stock options granted under the 2020 Plan cannot be less than 100% of the fair value of the common stock on the grant date. The term and vesting period of each option shall be stated in the underlying agreements. However, the term shall be no more than ten years from the date of grant. The stock options generally vest over a four-year period. If stock options are granted to an optionee who, at the grant date, owns the Company common stock representing more than ten percent of the voting power of all classes of stock of the Company, then the term of the stock option shall be five years from the date of grant and the stock option exercise price is equal to 110% of the fair value at the date of grant.

Following is a summary of the Company's stock option plan activity and related information for the year ended December 31, 2021:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Intrinsic Value (thousands)
Balance at January 1, 2021	4,738,607	\$ 10.34	8.34	
Granted	7,228,445	8.81		
Exercised	(583,332)	3.39		
Forfeited/Cancelled	(1,484,013)	10.83		
Balance at December 31, 2021	9,899,707	\$ 9.57	8.57	\$ 2,938
Options vested and expected to vest as of December 31, 2021	9,899,707	\$ 9.57	8.57	\$ 2,938
Options vested and exercisable as of December 31, 2021	3,033,767	\$ 9.81	7.43	\$ 2,792

The aggregate intrinsic value of options exercised during the years ended December 31, 2021 and 2020 was \$3.4 million and \$2.4 million, respectively, determined as of the date of exercise. The Company received \$2.0 million and \$0.2 million in cash from options exercised during the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, total unrecognized compensation cost related to stock options was \$42.8 million, and the weighted-average period over which this cost is expected to be recognized is approximately 2.9 years.

The weighted-average fair value of options granted during the years ended December 31, 2021 and 2020 was \$6.12 and \$8.65 per share, respectively. Total fair value of shares vested during the years ended December 31, 2021 and 2020 was \$16.7 million and \$6.9 million, respectively.

The assumptions that the Company used to determine the fair value of options granted to employees, non-employees and directors were as follows:

	Year Ended December 31,	
	2021	2020
Risk-free interest rate	0.5%–1.3%	0.4%–1.4%
Expected volatility	82.2–84.3%	79–86%
Expected term (years)	5.5–6.0	5.5–6.0
Dividend yield	—	—

*Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

*Expected volatility*—The expected volatility is estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.

*Expected term*—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.

*Expected dividend*—The Company has never paid dividends on its common stock, and has no plans to pay any dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

In July 2020, the Company's board of directors and stockholders approved and adopted the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective as of the pricing of the IPO. A total of 615,000 shares of common stock were approved to be initially reserved for issuance under the ESPP. The number of shares of common stock available for issuance under the ESPP is automatically increased on the first day of each calendar year during the first ten-years of the term of the ESPP, beginning with January 1, 2021 and ending with January 1, 2030, by an amount equal to the lesser of (i) 1% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year, (ii) 1,230,000 shares of common stock or (iii) such

lesser amount as determined by the Company's board of directors. Under the 2020 ESPP, substantially all employees can elect to have up to 15% of their annual compensation withheld to purchase up to 3,000 shares of common stock per purchase period, subject to certain limitations. The shares of common stock can be purchased over an offering period of six months and at a price of 85% of the fair market value per share of common stock on the first trading day of the applicable offering period or on the exercise date of the applicable offering period, whichever is less. Under applicable accounting guidance, the 2020 ESPP is classified as a compensatory plan. The initial purchase period commenced in March 2021. For the year ended December 31, 2021, the assumptions used to estimate the fair value of shares purchasable under the ESPP using the Black-Scholes valuation model included risk-free interest rate of 0.05%, expected volatility ranging from 74.8% to 87.9%, expected term of 0.5 years and zero dividend yield. During the year ended December 31, 2021, a total of 79,367 shares were purchased by the Company's employees under the 2020 ESPP resulting in net proceeds of \$0.5 million.

The Company recorded total stock-based compensation expense in the following expense categories of the accompanying consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2021	2020
Research and development	\$ 8,090	\$ 3,872
General and administrative	8,614	3,348
Total stock-based compensation expense	<u>\$ 16,704</u>	<u>\$ 7,220</u>

## Note 11. Commitments and Contingencies

### Operating Leases

As of December 31, 2021, the Company had operating leases for manufacturing, laboratory and office space in San Diego, California consisting of approximately 87,000 square feet with remaining lease terms of 8.0 years. The manufacturing and laboratory and office space lease agreements include two options to extend the term for a period of 5 years each. Additionally, the Company had operating leases for dedicated manufacturing suites at its contract manufacturers with remaining lease terms of up to 2 years.

In October 2018, the Company entered into a lease agreement for a facility in San Diego, California to be used for research and development and administrative activities. The lease term commenced on April 1, 2019 and will expire on December 31, 2029.

In October 2019, the Company entered into a lease amendment to expand the existing premises. The lease term for the additional premises commenced on July 29, 2020 and will expire on December 31, 2029. The lease amendment provided for additional tenant reimbursements of \$1.5 million and as costs were incurred, the Company performed additional analysis to determine treatment based on the type of leasehold improvement. Both the original lease and amendment provides for rent abatements and scheduled increases in base rent. In connection with the lease and its amendment, the Company made cash security deposits in the amount of \$0.3 million, included in other long-term assets in the Company's consolidated balance sheets as of December 31, 2021 and 2020.

In July 2019, the Company entered into a lease agreement for a facility in San Diego, California that was retrofitted to Good Manufacturing Practice standards and is used for manufacturing in its early-stage clinical trials. The lease term commenced on June 26, 2020 and will expire on December 31, 2029. The lease provided for tenant improvements of \$2.9 million and as costs were incurred, the Company performed analysis to determine treatment based on the type of leasehold improvement. As of December 31, 2020, all costs were incurred, and construction was completed. The lease provides for rent abatements and scheduled increases in base rent. In connection with the lease, the Company made a one-time cash security deposit in the amount of \$0.1 million, included in other long-term assets in the Company's consolidated balance sheets as of December 31, 2021 and 2020.

Upon adoption of ASC 842 on January 1, 2020, the Company determined its leases meet the criteria of operating leases. Further, upon adoption of ASC 842, the Company determined it was the owner of certain tenant improvements but did not control the construction project and therefore the fair value of the building was derecognized and costs incurred by the Company related to the tenant improvements of \$13.3 million were recorded as leasehold improvements in property and equipment, net on the consolidated balance sheet as of December 31, 2020 and will be depreciated over the remaining lease term.

In connection with the adoption of ASC 842, the Company recognized initial lease receivables of \$2.7 million, right-of-use ("ROU") lease assets of \$22.3 million, which was adjusted for the deferred rent balance of \$2.3 million and an initial lease liability of \$27.3 million, with respect to the existing leases. The leases in San Diego include an option to extend, which was not recognized as part of the lease liability and ROU lease assets as it was not reasonably certain the Company would exercise the extension right. Additionally, under lease accounting guidance, the Company had been the deemed owner under construction of the manufacturing facility. Upon the adoption of ASC 842 the Company derecognized the amounts previously presented on its balance sheet related to its manufacturing facility including construction in progress of \$2.1 million within property and equipment, and the construction financing obligation of \$2.5 million recorded within other long-term liabilities and \$0.3 million of other receivables within prepaid and other current assets as of December 31, 2019. The Company also recorded a cumulative adjustment to the opening balance of accumulated deficit of \$0.1 million as of January 1, 2020.

During the years ended December 31, 2021 and 2020, the Company recognized \$6.3 million and \$6.0 million, respectively, of operating lease expense. The Company recognized an immaterial amount of variable operating lease expense for the twelve months ended December 31, 2021. During the year ended December 31, 2021, the Company paid \$6.1 million in cash payments for its operating leases. As of December 31, 2021, the weighted average remaining lease term for operating leases was 7.4 years and the weighted-average discount rate for operating leases was 8.92%.

As of December 31, 2021, maturities of lease liabilities were as follows (in thousands):

<b>Year ending December 31,</b>	
2022	\$ 6,577
2023	5,723
2024	4,814
2025	4,958
2026	5,107
Thereafter	16,259
Total future lease payments	43,438
Imputed interest	(11,597)
Total lease liability balance	31,841
Less current portion of lease liability	6,337
Lease liability, net of current portion	<u>\$ 25,504</u>

#### ***Lease Agreement not Commenced as of December 31, 2021***

In October 2021, the Company entered into a sublease agreement for a facility in San Diego, California consisting of approximately 24,000 square feet to be used for administrative activities. The lease term commenced in March 2022 and will expire on December 31, 2025. Future payments under the lease agreement are approximately \$5.2 million.

#### ***Indemnification Agreements***

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and certain of its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

#### ***License Agreement with Janssen Biotech Inc.***

In August 2015, the Company entered into a license agreement ("Janssen Agreement") with Janssen pursuant to which the Company obtained exclusive worldwide rights to research, develop, manufacture and commercialize pharmaceutical products comprising autologous CAR-modified T-cells or any CAR-modified natural killer or CAR-modified natural-killer-like cells expressing certain Centyrin molecules or Centyrin CAR molecules for the treatment or prevention of any disease in humans. Pursuant to the Janssen Agreement, the Company paid Janssen an upfront fee of \$0.2 million. Based on milestone developments, the Company has paid an additional \$4.0 million through December 31, 2021. The Company is required to pay Janssen up to an aggregate of \$75.8 million upon the achievement of certain clinical, regulatory and sales milestones for the first licensed product and up to an aggregate of \$46.8 million upon the achievement of certain clinical, regulatory and sales milestones for each licensed product thereafter. The Company is also obligated to pay, on a product-by-product and country-by-country basis, royalties in the low single-digit percentage range on annual net sales.

***April 2017 Commercial License Agreement with TeneoBio, Inc.***

In April 2017, the Company entered into a commercial license agreement (the “2017 TeneoBio Agreement”) with TeneoBio, Inc. (“TeneoBio”) pursuant to which the Company obtained exclusive worldwide rights to use and develop pharmaceutical products comprising allogeneic T-cells expressing a CAR molecule containing certain heavy chain sequences provided by TeneoBio.

Pursuant to the 2017 TeneoBio Agreement, the Company has paid TeneoBio \$0.5 million through the Company’s selection of the antibodies licensed under the 2017 TeneoBio Agreement. The Company is required to pay TeneoBio up to an aggregate of \$20.5 million upon the first achievement of certain clinical and regulatory milestones for any allogeneic product and up to an aggregate of \$20.5 million upon the first achievement of certain clinical and regulatory milestones for any autologous product. The Company is also obligated to pay, on a product-by-product and country-by-country basis, a royalty in the low single-digit percentage on net sales of any licensed products.

***August 2018 Commercial License Agreement with TeneoBio, Inc.***

In August 2018, the Company entered into a commercial license agreement (the “2018 TeneoBio Agreement”) with TeneoBio pursuant to which the Company obtained exclusive rights to research, develop and commercialize up to a certain number of targets from TeneoBio. Pursuant to the 2018 TeneoBio Agreement, the Company has paid TeneoBio an upfront fee of \$4.0 million. The Company is required to pay TeneoBio up to an aggregate of \$31.0 million upon the first achievement of certain clinical and regulatory milestones for each product, none of which have been met. The Company is also obligated to pay, on a product-by-product and country-by-country basis, a royalty in the low single-digit percentage on net sales of any licensed products.

***October 2019 License Agreement with Genus Oncology, LLC***

In October 2019, the Company entered into a license agreement (the “Genus Agreement”) with Genus Oncology, LLC (“Genus”), pursuant to which the Company paid Genus an upfront fee of \$1.5 million and Genus granted the Company the option, which is exercisable for an additional \$1.5 million fee, to obtain an exclusive worldwide license to research, develop and commercialize pharmaceutical products incorporating CAR cells expressing antibodies and derivatives thereof targeting MUC1.

Pursuant to the Genus Agreement, the Company is also required to pay Genus up to an aggregate of \$71.0 million upon first achievement of certain clinical, regulatory and sales milestones for any Genus licensed product and companion diagnostics. The Company is also obligated to pay, on a product-by-product and country-by-country basis, tiered royalties in the low to mid-single-digit percentage on net sales of any Genus licensed products and related companion diagnostics.

***Legal Contingencies***

In the ordinary course of business, the Company may face claims brought by third parties against the Company. The Company does not believe that there is any litigation, asserted or unasserted claim pending that could, individually or in the aggregate, have a material adverse effect on the Company’s results of operations or financial condition.

**Note 12. Income Taxes**

The components of the pretax loss from operations were all attributed to the United States. There was no income tax expense or benefit for the years ended December 31, 2021 and 2020.

The (benefit from) provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory federal income tax rate to pretax income as a result of the following differences as of (in thousands):

	Year Ended December 31,	
	2021	2020
Federal statutory rate	\$ (26,245)	\$ (27,253)
Adjustments for tax effects of:		
Tax credits	(22,448)	(10,735)
State taxes, net	(7,575)	(8,581)
Unrecognized tax benefits	3,431	2,445
Stock-based compensation	2,308	956
Permanent adjustments	53	134
Other, net	(192)	(27)
Change in valuation allowance	50,668	43,061
Total	<u>\$ —</u>	<u>\$ —</u>

Significant components of the Company's deferred tax assets and liabilities consist of the following as of (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating losses	\$ 98,815	\$ 65,058
Income tax credit carryforwards	33,524	15,727
Lease liabilities	8,885	8,388
Deferred revenue	2,280	—
Accrued expenses	2,233	1,855
Amortization	1,406	1,558
Grant income	1,114	6,648
Other, net	2,430	982
Total deferred tax assets	<u>150,687</u>	<u>100,216</u>
Deferred tax liabilities:		
Right of use assets	(7,305)	(6,934)
Depreciation	(1,308)	(1,877)
Acquired indefinite lived intangibles	(368)	(369)
Total deferred tax liabilities	<u>(8,981)</u>	<u>(9,180)</u>
Valuation allowance	(141,761)	(91,091)
Net deferred tax liability	<u>\$ (55)</u>	<u>\$ (55)</u>

The realization of deferred tax assets may be dependent on the Company's ability to generate sufficient income in future years in the associated jurisdiction to which the deferred tax assets relate. The Company considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. A valuation allowance of \$141.8 million has been recorded as of December 31, 2021, as compared to \$91.1 million as of December 31, 2020. The valuation allowance is based on management's assessment that it is more likely than not that the Company will not have taxable income in the foreseeable future.

Deferred tax liabilities associated with indefinite-life intangibles cannot be considered a source of income to support the realization of deferred tax assets because the reversal of these deferred tax liabilities is considered indefinite. However, as the Company has an indefinite-life asset with an unlimited loss carryforward period within the same jurisdiction, and of appropriate character, the deferred tax liability associated with the indefinite-life intangible constitutes a source of taxable income to support the realization of the deferred tax asset, since both have indefinite reversal or expiration periods.

As of December 31, 2021, the Company had federal and state net operating loss carryforwards of \$23.3 million and \$350.8 million, respectively, which begin to expire in 2032 and the Company had federal net operating loss carryforwards that do not expire but utilization is limited to 80% of taxable income for any given tax year in the amount of \$329.9 million.

As of December 31, 2021, the Company had federal orphan drug credits and research and development credits and state research and development tax credits of \$33.2 million and \$11.8 million, respectively. The federal research and development tax credits will begin to expire in 2032, while the state credits do not expire.

Additionally, the utilization of the net operating loss and research and development tax credit carryforwards is subject to an annual limitation under Section 382 of the Internal Revenue Code. Future ownership changes as determined under Section 382 could further limit the utilization of net operating loss carryforwards. Due to the existence of the valuation allowance, future changes in the deferred tax assets related to these tax attributes will not impact the Company's effective tax rate.

The Company is subject to taxation in the U.S. and state jurisdictions. As of December 31, 2021, the Company's tax years beginning 2012 to date are subject to examination by federal and other state taxing authorities due to the carry forward of unutilized net operating losses and research and development tax credits. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. The Company is not currently under examination by the IRS or state and local tax authorities.

As of December 31, 2021, the Company had unrecognized tax benefits of \$9.5 million, determined as follows:

	December 31,	
	2021	2020
Balance at beginning of year	\$ 5,457	\$ 2,470
Increase for current year positions	4,105	3,211
Decrease for prior year positions	(68)	(224)
Balance at the end of year	<u>\$ 9,494</u>	<u>\$ 5,457</u>

These unrecognized tax benefits are not expected to change within the next twelve months. Of the \$9.5 million of unrecognized tax benefits, zero would impact the effective tax rate due to the valuation allowance, if reversed. The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2021, there are no accrued interest or penalties.

#### Note 13. Employee Benefit Plan

The Company has a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the Board of Directors. Total contributions by the Company during the years ended December 31, 2021 and 2020 were \$0.9 million and \$0.6 million, respectively.

#### Note 14. Net Loss Per Share

Net loss per share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options and from purchases under the ESPP, as well as from the possible conversion of the Company's preferred stock and exercise of the outstanding warrants.

The Company's potentially dilutive securities, which include warrants to purchase common stock, common stock options and common stock from the ESPP, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. 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 Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2021	2020
Stock options to purchase common stock	9,899,707	4,738,607
Warrants to purchase convertible preferred stock (as converted to common stock)	121,122	121,122
ESPP shares	5,310	—
	<u>10,026,139</u>	<u>4,859,729</u>

#### Note 15. Subsequent Events

In February 2022, the Company entered into a new Loan and Security Agreement (“2022 Loan Agreement”) with Oxford. Pursuant to the terms of the 2022 Loan Agreement, the Company borrowed \$60.0 million in term loans, a portion of which was used to repay the balance outstanding under the 2021 Amended Loan Agreement. Under the 2022 Loan Agreement the interest-only period is through April 1, 2025, with interest-only payments through March 1, 2025, followed by 23 equal monthly payments of principal and applicable interest. Upon the satisfaction of certain conditions set forth in the 2022 Loan Agreement, the interest-only period may be extended through April 1, 2026, followed by 11 equal monthly payments of principal and applicable interest. As a result, all amounts outstanding under the 2022 Loan Agreement will mature on February 1, 2027. Upon occurrence of a qualifying equity event, the interest-only period is subject to an extension to 48 months followed by 11 equal monthly payments of principal and applicable interest. In connection with the repayment of the balance outstanding under the 2021 Amended Loan Agreement, the Company incurred amendment and final payment fees of \$1.6 million previously due on the earlier of (i) the maturity date, (ii) acceleration of any Term Loan, or (iii) the prepayment of the Term Loans. The Company has an option to repay the outstanding debt under the 2022 Loan Agreement at any time in increments of \$5.0 million, subject to a prepayment fee of 1.0% if the term loans are prepaid on or prior to February 22, 2024, after which no prepayment penalty would be applied. Consistent with the 2021 Amended Loan Agreement, there is a 7.5% final payment fee payable on the earlier of (i) the new maturity date, (ii) acceleration of the new loan, or (iii) the prepayment of the new loan.

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

None.

**Exhibit Index**

<b>Exhibit Number</b>	<b>Description</b>
2.1^	<a href="#"><u>Agreement and Plan of Merger and Reorganization, by and among the Registrant, Hermes Merger Sub I, Inc., Hermes Merger Sub II, LLC, Vindico NanoBioTechnology, Inc. and Christopher Young as Stockholders' Representative, dated October 10, 2016, as amended (incorporated by reference to Exhibit 2.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).</u></a>
3.1	<a href="#"><u>Amended and Restated Certificate of Incorporation, of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on July 14, 2020).</u></a>
3.2	<a href="#"><u>Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on July 14, 2020).</u></a>
4.1	<a href="#"><u>Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).</u></a>
4.2^	<a href="#"><u>Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated June 24, 2020 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-239321), filed with the SEC on July 6, 2020).</u></a>
4.3	<a href="#"><u>Form of Warrant issued to Oxford Finance LLC, dated July 25, 2017 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).</u></a>
4.4	<a href="#"><u>Form of Warrant issued to Oxford Finance LLC, dated August 13, 2018 (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).</u></a>
4.5	<a href="#"><u>Form of Warrant issued to Oxford Finance LLC, dated February 11, 2019 (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).</u></a>
4.6	<a href="#"><u>Description of Common Stock (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-K (File No. 001-39376), filed with the SEC on March 11, 2021).</u></a>
10.1+	<a href="#"><u>Form of Indemnity Agreement, by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-239321), filed with the SEC on June 19, 2020).</u></a>
10.2+	<a href="#"><u>Poseida Therapeutics, Inc. 2015 Equity Incentive Plan, as amended, and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-239321), filed with the SEC on July 6, 2020).</u></a>
10.3+	<a href="#"><u>Poseida Therapeutics, Inc. 2020 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-239321), filed with the SEC on July 6, 2020).</u></a>
10.4+	<a href="#"><u>Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the Poseida Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39376), filed with the SEC on November 9, 2021).</u></a>
10.5+	<a href="#"><u>Poseida Therapeutics, Inc. 2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-239321), filed with the SEC on July 6, 2020).</u></a>
10.6+	<a href="#"><u>Poseida Therapeutics, Inc. Severance and Change in Control Plan and Form of Participation Agreement (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-239321), filed with the SEC on July 6, 2020).</u></a>
10.7+^	<a href="#"><u>Amended and Restated Executive Employment Agreement, by and between the Registrant and Eric Ostertag, dated February 1, 2022 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on February 1, 2022).</u></a>
10.8+	<a href="#"><u>Amended and Restated Participation Agreement, by and between the Registrant and Eric Ostertag, dated February 1, 2022 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on February 1, 2022).</u></a>
10.9+^	<a href="#"><u>Amended and Restated Executive Employment Agreement, by and between the Registrant and Mark Gergen, dated February 1, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on February 1, 2022).</u></a>
10.10+	<a href="#"><u>Amended and Restated Participation Agreement, by and between the Registrant and Mark Gergen, dated February 1, 2022 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-39376), filed with the SEC on February 1, 2022).</u></a>

- 10.11+^ [Offer Letter, by and between the Registrant and Matthew Spear, dated June 13, 2016 \(incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.12+^ [Offer Letter, by and between the Registrant and Kerry Ingalls, dated July 29, 2019 \(incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.13+^ [Offer Letter, by and between the Registrant and Johanna Mylet, dated June 8, 2015 \(incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.14+ [Poseida Therapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy \(incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K \(File No. 001-39376\), filed with the SEC on July 26, 2021\),](#)
- 10.15+ [Poseida Therapeutics, Inc. 2022 Inducement Plan \(incorporated by reference to Exhibit 99.4 to the Registrant's Registration Statement on Form S-8 \(File No. 333-262869\), filed with the SEC on February 18, 2022\),](#)
- 10.16+ [Forms of Grant Notice, Stock Option Agreement, Notice of Exercise, Restricted Stock Unit Grant Notice and Award Agreement under the Poseida Therapeutics, Inc. 2022 Inducement Plan \(incorporated by reference to Exhibit 99.5 to the Registrant's Registration Statement on Form S-8 \(File No. 333-262869\), filed with the SEC on February 18, 2022\),](#)
- 10.17\* [License Agreement, by and between the Registrant and Janssen Biotech, Inc., effective August 3, 2015 \(incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.18\* [Commercial License Agreement, by and between the Registrant and TeneoBio, Inc., effective April 27, 2017 \(incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.19\* [Commercial License Agreement, by and between the Registrant and TeneoBio, Inc., effective August 3, 2018 \(incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.20\* [License Agreement, by and between the Registrant and Helmholtz-Zentrum München—Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH, dated May 20, 2016 \(incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.21\* [License Agreement, by and between the Registrant and Genus Oncology, LLC, effective October 24, 2019 \(incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.22\* [Collaboration and License Agreement, by and between the Registrant and Takeda Pharmaceuticals USA, Inc., effective October 11, 2021,](#)
- 10.23^ [Loan and Security Agreement, by and among the Registrant, Vindico NanoBioTechnology, LLC and Oxford Finance LLC, dated February 22, 2022,](#)
- 10.24 [Lease, by and between the Registrant and BMR-9360-9390 Towne Centre LP, dated October 1, 2018, as amended on October 4, 2019 and March 11, 2020 \(incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.25 [Lease, by and between the Registrant and BMR-Eastgate Mall LP, dated July 12, 2019 \(incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 \(File No. 333-239321\), filed with the SEC on June 19, 2020\),](#)
- 10.26 [Controlled Equity OfferingSM Sales Agreement, by and between the Registrant and Cantor Fitzgerald & Co., dated August 13, 2021 \(incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 \(File No. 333-258804\), filed with the SEC on August 13, 2021\),](#)
- 10.27\* [Amended and Restated License Agreement, by and between the Registrant and Helmholtz-Zentrum München—Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH, executed as of March 12, 2021 \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q \(File No. 001-39376\), filed with the SEC on May 11, 2021\),](#)
- 21.1 [Subsidiaries of the Registrant,](#)
- 23.1 [Consent of Independent Registered Public Accounting Firm,](#)
- 24.1 [Power of Attorney \(reference is made to the signature page hereto\),](#)
- 31.1 [Certification of Principal Executive Officer Pursuant to Rules 13a-14\(a\) and 15d-14\(a\) Under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002,](#)
- 31.2 [Certification of Principal Financial Officer Pursuant to Rules 13a-14\(a\) and 15d-14\(a\) Under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002,](#)

32.1	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

+ Indicates management contract or compensatory plan.

\* Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted by means of marking such portions with asterisks because the Registrant has determined that the information is not material and would likely cause competitive harm to the Registrant if publicly disclosed.



CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [\*\*\*], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

EXECUTION VERSION

**COLLABORATION AND LICENSE AGREEMENT**

by and between

**Poseida Therapeutics, Inc.**

and

**Takeda Pharmaceuticals USA, Inc.**

**Dated as of October 11, 2021**

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## **COLLABORATION AND LICENSE AGREEMENT**

**THIS COLLABORATION AND LICENSE AGREEMENT** (this “**Agreement**”) is entered into as of October 11, 2021 (the “**Effective Date**”), by and between Takeda Pharmaceuticals USA, Inc., a Delaware corporation having a place of business at 95 Hayden Avenue, Lexington, MA 02421, United States (“**Takeda**”), and Poseida Therapeutics, Inc., a Delaware corporation, having a place of business at 9390 Towne Centre Drive, Suite 200, San Diego, CA 92121 (“**Poseida**”).

### **INTRODUCTION**

**WHEREAS**, Takeda is in the business of developing and delivering new treatments in multiple therapeutic areas, including rare diseases.

**WHEREAS**, Poseida has a suite of technology platforms with applicability to create transformative, curative therapies for rare diseases.

**WHEREAS**, the Parties desire to collaborate to evaluate and apply Poseida’s current and next generation technology platforms to develop Licensed Products (as defined herein) targeted to rare diseases.

**WHEREAS**, Takeda shall have the option to exclusively license the Licensed IP (as defined herein) for designated Indications (as defined herein), and thereafter Takeda would independently assume further development, manufacturing and commercialization related to such Licensed Products on the terms and conditions set forth in this Agreement.

**NOW, THEREFORE**, in consideration of the respective representations, warranties, covenants and agreements contained herein, and for other valuable consideration, the receipt and adequacy of which are hereby acknowledged, Poseida and Takeda agree as follows:

### **ARTICLE I**

#### **DEFINITIONS**

1.1 **Definitions.**

For the purpose of this Agreement, the following terms, whether used in singular or plural form, shall have the respective meanings set forth below:

- 1.1.1 “**Acquired Party**” has the meaning set forth in Section 5.7.
- 1.1.2 “**Acquirer**” has the meaning set forth in Section 5.7.
- 1.1.3 “**Action**” means any legal action, claim, suit or proceeding.
- 1.1.4 “**Additional Indication License Option**” has the meaning set forth in Section 3.3(b)(i).
- 1.1.5 “**Additional Indication Option Period**” has the meaning set forth in Section 3.3(b)(i).
- 1.1.6 “**Additional Indication Program**” has the meaning set forth in Section 3.3(b)(i).
- 1.1.7 “**Additional Indication Program Notice**” has the meaning set forth in Section 3.3(b)(i).

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1.1.8 “**Additional Technology Transfer**” has the meaning set forth in Section 4.4(b).

1.1.9 “**Affiliate**” means, with respect to a particular Person, any other Person that controls, is controlled by or is under common control with such Person. For the purposes of this definition, the word “**control**” (including, with correlative meaning, the terms “**controlled by**” or “**under the common control with**”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, by contract or otherwise.

1.1.10 “**Agreement**” has the meaning set forth in the Preamble, and shall include, for the avoidance of doubt, all Exhibits hereto.

1.1.11 “**Alliance Manager**” has the meaning set forth in Section 2.4(a).

1.1.12 “**Applicable Accounting Standards**” means (a) with respect to Takeda, International Financial Reporting Standards (“**IFRS**”), (b) with respect to Poseida, United States generally accepted accounting principles (“**GAAP**”), and (c) with respect to any Related Party, GAAP or IFRS, as applicable, in each case as generally and consistently applied throughout such Party’s or its Related Party’s organization.

1.1.13 “**Arising IP**” has the meaning set forth in Section 7.1.

1.1.14 “**Arising Product IP**” has the meaning set forth in Section 7.2(b)(i)(2).

1.1.15 “**Arising Product Patent**” has the meaning set forth in Section 7.3(a).

1.1.16 “**Audit Arbitrator**” has the meaning set forth in Section 6.9.

1.1.17 “**Availability**” or “**Available**” means, as of the date of Poseida’s receipt of the Additional Indication Program Notice or Further Indication Program Notice, as applicable, that an Indication is not (a) the subject of [...\*\*\*...], or (b) the subject of [...\*\*\*...].

1.1.18 “**Bankrupt Party**” has the meaning set forth in Section 5.5.

1.1.19 [...\*\*\*...].

1.1.20 “**Biosimilar Product**” means, with respect to a Licensed Product in a country, [...\*\*\*...]

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[...\*\*\*...].

1.1.21 “**BLA**” means a Biologics License Application, New Drug Application, Marketing Authorization Application or similar application or submission filed with a Regulatory Authority in a country or group of countries to obtain Regulatory Approval for a biological, pharmaceutical or other therapeutic or prophylactic product in that country or in that group of countries, and all supplements and amendments that may be filed with respect to the foregoing.

1.1.22 “**Breaching Party**” has the meaning set forth in [Section 10.3\(a\)](#).

1.1.23 “**Business Day**” means a day on which banking institutions in New York, New York and Tokyo, Japan are open for business.

1.1.24 “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of each Calendar Year; *provided* that (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and (b) the last Calendar Quarter of the Term shall end on the last day of the Term.

1.1.25 “**Calendar Year**” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; *provided* that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and (b) the last Calendar Year of the Term shall end on the last day of the Term.

1.1.26 “**Candidate Selection**” means selection by Takeda of a product candidate arising from the Collaboration, that comprises [...\*\*\*...] (a) [...\*\*\*...] or (b) [...\*\*\*...] (such candidate, a “**Selected Candidate**”).

1.1.27 “**Cas-CLOVER**” has the meaning set forth in [Section 1.1.125](#).

1.1.28 “**Change of Control**” means, with respect to a Person, any of the following: (a) the sale or disposition of all or substantially all of the assets of such Person or its direct or indirect controlling Affiliate to a Third Party, other than to an entity of which more than fifty percent (50%) of the voting capital stock are owned after such sale or disposition by shareholders of such Person or its direct or indirect controlling Affiliate (in either case, whether directly or indirectly through any parent entity); or (b) (i) the acquisition by a Third Party, alone or together with any of its Affiliates, other than an employee benefit plan (or related trust) sponsored or maintained by such Person or any of its Affiliates, of more than fifty percent (50%) of the outstanding shares of voting capital stock of such Person or its direct or indirect controlling Affiliate, or (ii) the acquisition, merger or consolidation of such Person or its direct or indirect controlling Affiliate with or into another Person, other than, in the case of this clause (b), an acquisition or a

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merger or consolidation of such Person or its controlling Affiliate in which the holders of shares of voting capital stock of such Person or its controlling Affiliate, as the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Third Party or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation, and in each case (a) or (b), whether through a single transaction or a series of related transactions.

1.1.29 “**Clinical Trial**” means (a) any Phase 1 Clinical Trial, Phase 2 Clinical Trial or Phase 3 Clinical Trial, (b) such other tests and studies in human subjects that are required by Law or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Licensed Product for an Indication, and (c) any open label extension study of a Licensed Product; *provided, however*, that solely for the purposes of determining milestone payments required under ARTICLE VI, “Clinical Trial” shall exclude any investigator initiated sponsored research.

1.1.30 “**CMO Agreement**” has the meaning set forth in Section 4.5(b).

1.1.31 “**Collaboration**” means the collaboration between the Parties under this Agreement for the activities under the Platform Evaluation Work Plan and the performance of the Research Activities during the applicable Research Period.

1.1.32 “**Collaboration Infringement**” has the meaning set forth in Section 7.6(e).

1.1.33 “**Combination Product**” means [...\*\*\*...].

1.1.34 “**Commercial Milestone**” has the meaning set forth in Section 6.5.

1.1.35 “**Commercial Milestone Payment**” has the meaning set forth in Section 6.5.

1.1.36 “**Commercialization**” or “**Commercialize**” means, with respect to a Licensed Product, activities directed to the preparation for sale or sale of a Licensed Product, including activities related to marketing, promoting, detailing, distributing, importing, having imported, exporting, having exported, selling or offering to sell, or seeking to obtain reimbursement for, such Licensed Product, whether before or after Regulatory Approval for such Licensed Product has been obtained.

1.1.37 “**Commercially Reasonable Efforts**” means, [...\*\*\*...]

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[...\*\*\*...].

1.1.38 “**Competing Program**” has the meaning set forth in [Section 5.7\(b\)](#).

1.1.39 “**Confidential Information**” of a Party means the terms of this Agreement and [...\*\*\*...].

1.1.40 “**Confidentiality Agreement**” means that certain Confidentiality Agreement by and between Poseida and Takeda, dated of as

[...\*\*\*...].

1.1.41 “**Control**” or “**Controlled**” means, with respect to any Know-How, Patent Right or other Intellectual Property right and a Party, subject to [Section 5.7](#), the ability of such Party or its Affiliates (whether by ownership or license, other than pursuant to a license granted under this Agreement) to assign, transfer or grant access to, or a license or sublicense of, or grant the ability to prosecute, maintain or enforce, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party[...\*\*\*...].

1.1.42 “**Cover**” or “**Covered**” means, with respect to Know-How or Patent Rights and any Licensed Product, that, in the absence of Takeda obtaining ownership of or a license to such Know-How or Patent Rights, the Exploitation of such Licensed Product by Takeda would infringe or misappropriate such Know-How or Patent Rights.

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1.1.43 **“Debarred”** or **“Debarment”** means (a) being debarred, or being subject to a pending debarment, pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, (b) being listed by any federal or state agencies as excluded, debarred, suspended or otherwise made ineligible to participate in federal or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or being subject to any pending process by which any such listing, exclusion, debarment, suspension or other ineligibility could occur, (c) being disqualified by any government or regulatory agency from performing specific services, or being subject to a pending disqualification proceeding, or (d) being convicted of or pleading *nolo contendere* to a criminal offense related to the provision of healthcare items or services or being subject to any pending criminal Action related to the provision of healthcare items or services.

1.1.44 **“Develop”** or **“Development”** means, with respect to a product, discovery, research, preclinical development, clinical development, and regulatory activities with respect to such product, including test method development and stability testing, design, compatibility testing, toxicology, animal efficacy studies, formulation, quality assurance/quality control development, statistical analysis, clinical studies, regulatory affairs, regulatory approval (including the preparation and submission of applications for such regulatory approval) and registration, chemical development, manufacturing development, packaging development and manufacturing and development documentation efforts in support of development activities anywhere in the world, whether before or after regulatory approval for such product has been obtained.

1.1.45 **“Development and Regulatory Milestone”** has the meaning set forth in [Section 6.4](#).

1.1.46 **“Development and Regulatory Milestone Payment”** has the meaning set forth in [Section 6.4](#).

1.1.47 **“Disclosing Party”** has the meaning set forth in [Section 8.1\(a\)](#).

1.1.48 **“Dollars”** and **“\$”** means United States dollars.

1.1.49 **“EMA”** means the European Medicines Agency and any successor Governmental Authority having substantially the same function.

1.1.50 [...\*\*\*...].

1.1.51 **“Excess Cost”** has the meaning set forth in [Section 3.4\(a\)](#).

1.1.52 **“Effective Date”** has the meaning set forth in the Preamble.

1.1.53 **“Excluded In-License Agreements”** means those agreements set forth on [Exhibit 1.1.53](#).

1.1.54 **“Executive Officer”** means (a) with respect to Takeda, its President of Research and Development or another senior executive officer or their respective designee and (b) with respect to Poseida, its Chief Executive Officer (or his or her designee).

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- 1.1.55 “**Exploit**” or “**Exploitation**” means to Develop, have Developed, use, Manufacture, have Manufactured, sell, have sold, offer for sale, Commercialize, import, export, register, and otherwise exploit a Licensed Product.
- 1.1.56 “**FDA**” means the United States Food and Drug Administration or any successor Governmental Authority having substantially the same function.
- 1.1.57 [...\*\*\*...].
- 1.1.58 “**Field**” means all uses.
- 1.1.59 “**Final Data Package**” means the final written data package delivered by Poseida to Takeda promptly, and in any case within [...\*\*\*...], after the completion of the activities under the Platform Evaluation Work Plan, containing all data, findings, results and information described in the Platform Evaluation Work Plan or set forth on Exhibit 1.1.59.
- 1.1.60 “**First Commercial Sale**” means [...\*\*\*...].
- 1.1.61 “**FTE**” means, with respect to a Program, a full-time employee of Poseida dedicated to activities under the Program or full-time equivalent employee of Poseida based on a total of [...\*\*\*...] hours of scientific, technical or managerial activities under the Program per year.
- 1.1.62 “**FTE Costs**” means, with respect to Poseida for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of Poseida performing activities under a given Program in accordance with the applicable Research Plan.
- 1.1.63 “**FTE Rate**” means [...\*\*\*...] per FTE per year. [...\*\*\*...].
- 1.1.64 “**Further Indication License Option**” has the meaning set forth in Section 3.3(b)(ii).
- 1.1.65 “**Further Indication Option Period**” has the meaning set forth in Section 3.3(b)(ii).
- 1.1.66 “**Further Indication Program**” has the meaning set forth in Section 3.3(b)(ii).
- 1.1.67 “**Further Indication Program Notice**” has the meaning set forth in Section 3.3(b)(ii).
- 1.1.68 “**Governmental Authority**” means any applicable government authority, court, tribunal, arbitrator, agency, legislative body, commission or other instrumentality of (a) any government of any country or jurisdiction, (b) any state, province, county, city or other political subdivision thereof or (c) any supranational body.
- 1.1.69 “**Hemophilia A Milestone 1**” means [...\*\*\*...]

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[...\*\*\*...].

1.1.70 “**Hemophilia A Milestone 2**” means [...\*\*\*...].

1.1.71 “[...\*\*\*...]” has the meaning set forth in Exhibit 1.1.72.

1.1.72 “**In-License Agreements**” means any contract or agreement with a Third Party pursuant to which Poseida, during the Term, in-licenses or otherwise maintains Control of Patent Rights, Know-How or other Intellectual Property rights that constitute Licensed IP for purposes of this Agreement. The In-License Agreements existing as of the Effective Date, as set forth on Exhibit 1.1.72 (which, for clarity, subject to Section 5.2(g)(iii), exclude the Excluded In-License Agreements), are deemed Controlled by Poseida as of the Effective Date and additional payments by Takeda are not required thereunder.

1.1.73 “**IND**” means an application submitted to a Regulatory Authority to initiate human clinical trials, including (a) an Investigational New Drug application or any successor application or procedure filed with the FDA, (b) any equivalent of a U.S. Investigational New Drug application in any country outside the United States, and (c) all supplements and amendments that may be filed with respect to the foregoing.

1.1.74 “**Indemnified Party**” has the meaning set forth in Section 11.4.

1.1.75 “**Indemnifying Party**” has the meaning set forth in Section 11.4.

1.1.76 “**Indications**” means, collectively, the [...\*\*\*...] Indications and the [...\*\*\*...] Indications.

1.1.77 “**Initial Indication Program**” has the meaning set forth in Section 3.3(a)(i).

1.1.78 “**Initial Technology Transfer**” has the meaning set forth in Section 4.4(a)(i).

1.1.79 “**Intellectual Property**” means all intellectual property and proprietary rights, including (a) all inventions (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents, patent applications, and patent and invention disclosures, together with all provisionals, reissuances, continuations, continuations-in-part, divisions, revisions, extensions, and reexaminations thereof, (b) all trademarks, service marks, trade dress, logos, slogans, brand names, trade names, domain names, and business and product names, and all applications and registrations therefor, and all extensions and renewals thereof, and all goodwill of the business connected with the use of and symbolized by the foregoing, (c) all copyrights and copyrightable works, works of authorship (whether or not copyrightable), all mask

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works, industrial designs, and protectable designs, and all applications and registrations therefor, and all extensions and renewals thereof, (d) all trade secrets and confidential business information (including research and development, know-how, formulae, compositions, processes, techniques, methodologies, technical information, designs, industrial models, manufacturing, engineering and technical drawings, specifications, research records, records of inventions, test information, customer and supplier lists, customer data, pricing and cost information, and business and marketing plans and proposals), and (e) all rights to use all of the foregoing and all other rights in, to, and under the foregoing.

Agreement. 1.1.80 “**Invention**” means any invention or discovery, whether or not patentable, that is conceived, in whole or in part, under this

1.1.81 “[...\*\*\*...]” has the meaning set forth in Exhibit 1.1.53.

1.1.82 “**Joint Arising IP**” has the meaning set forth in Section 7.2(b)(iii).

1.1.83 “**Joint Manufacturing Working Group**” has the meaning set forth in Section 2.1(i).

Patents. 1.1.84 “**Joint Patents**” includes any Patent Rights under the Joint Arising IP, but excluding, for clarity, any Poseida Patents or Takeda

1.1.85 “**JSC**” has the meaning set forth in Section 2.1(a).

1.1.86 “**Know-How**” means any intangible information, including data, inventions (including, for clarity, Inventions), practices, methods, protocols, formulas, knowledge, know-how, trade secrets, processes, assays, skills, experience, techniques, governmental or regulatory information (including all regulatory materials submitted or required to be submitted to a Regulatory Authority, or received from a Regulatory Authority, in connection with a clinical trial, manufacturing or marketing authorization), and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical data and analytical and quality control data, patentable or otherwise.

1.1.87 “**Knowledge**” means the good faith understanding of the facts and information after performing a diligent investigation with respect to such facts and information, of [...\*\*\*...].

1.1.88 “**Law**” means any applicable law, statute, rule, regulation, ordinance or other pronouncement having the effect of law of any Governmental Authority, including any rules, regulations, regulatory guidelines or other requirements of any Regulatory Authorities, major national securities exchanges or major securities listing organizations that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder, including, to the extent applicable, current good clinical practice, good laboratory practice and good manufacturing practice.

1.1.89 “**License Option**” means each Additional Indication License Option and each Further Indication License Option, as applicable.

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applicable. 1.1.90 **“License Option Period”** means the Additional Indication Option Period and the Further Indication Option Period, as

1.1.91 **“Licensed IP”** means, collectively, the Licensed Know-How and the Licensed Patent Rights.

1.1.92 **“Licensed Know-How”** means all Know-How, including Know-How included in Poseida Background IP, Poseida Arising IP and Joint Arising IP, owned or otherwise Controlled by Poseida or any of its Affiliates as of the Effective Date, or during the Term, that is necessary or reasonably useful to Develop, Manufacture, Commercialize, use, sell, offer for sale, or otherwise Exploit Licensed Products for the Field in the Territory.

1.1.93 **“Licensed Patent Rights”** means any and all Patent Rights, including Patent Rights included in Poseida Background IP, Poseida Arising IP and Joint Arising IP, owned or otherwise Controlled by Poseida or any of its Affiliates as of the Effective Date, or during the Term, that are necessary or reasonably useful to Develop, Manufacture, Commercialize, use, sell, offer for sale, or otherwise Exploit Licensed Products for the Field in the Territory.

1.1.94 **“Licensed Product”** means any product that contains or incorporates a Selected Candidate, including all methods, forms, presentations, dosage strengths, dosage forms and formulations thereof, for administration by any method of delivery. For clarity, [...\*\*\*...].

1.1.95 [...\*\*\*...].

1.1.96 **“Losses”** means liabilities, costs, expenses, and losses, including reasonable legal expenses and attorneys’ fees.

1.1.97 **“Manufacture”** or **“Manufacturing”** means, with respect to a product and as applicable, all activities associated with the production, manufacture, supply, processing, filling, packaging, labeling, shipping, and storage of such product or any components thereof, including process and formulation development, process validation, stability testing, manufacturing scale-up, preclinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release.

1.1.98 **“Materials”** has the meaning set forth in Section 3.6.

1.1.99 **“Net Sales”** means for any period and for any country or other jurisdiction in the Territory, [...\*\*\*...]

[...\*\*\*...]

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[...\*\*\*...].

1.1.100 “**Non-Acquired Party**” has the meaning set forth in [Section 5.7](#).

1.1.101 “**Non-Bankrupt Party**” has the meaning set forth in [Section 5.5](#).

1.1.102 “**Non-Breaching Party**” has the meaning set forth in [Section 10.3\(a\)](#).

1.1.103 “**Out-of-Pocket Costs**” means amounts paid to permitted subcontractors (without mark-up) under arm’s length arrangements for services or material provided by them in performance of activities under the applicable Research Plan.

1.1.104 “**Party**” or “**Parties**” means Poseida or Takeda.

1.1.105 “**Patent Rights**” means patents, patent applications or provisional patent applications, utility models and utility model applications, design patents or registered industrial designs and design applications or applications for registration of industrial designs, and all substitutions, divisionals, continuations, continuation-in-part applications, continued prosecution applications, requests for continued examinations, reissues, reexaminations and extensions thereof, in any country of the world.

1.1.106 “**Patent Subcommittee**” has the meaning set forth in [Section 2.1\(f\)\(i\)](#).

1.1.107 “**Payload**” means a Poseida Payload, a Takeda Payload or any Public Domain Payload.

1.1.108 “**Person**” means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.1.109 “**Phase 1 Clinical Trial**” means a study of a Licensed Product, the principal purpose of which is a preliminary determination of safety, tolerability, pharmacological activity or pharmacokinetics in the target patient population, or a similar Clinical Trial prescribed by the applicable Regulatory Authorities, pursuant to Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(a), as amended, or an equivalent Clinical Trial required by a Regulatory Authority outside of the United States, in each case, sponsored by Takeda or its Affiliate or Sublicensee.

1.1.110 “**Phase 2 Clinical Trial**” means a study of a Licensed Product, the principal purpose of which is to evaluate preliminary efficacy and establish safety, appropriate dosage and pharmacological activity in the target patient population, or a similar Clinical Trial

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prescribed by the applicable Regulatory Authorities, pursuant to Law or otherwise, including the trials referred to in 21 C.F.R. § 312.21(b), as amended, or an equivalent Clinical Trial required by a Regulatory Authority outside of the United States, in each case, sponsored by Takeda or its Affiliate or Sublicensee. For purposes of this Agreement, a human clinical trial that combines elements of a Phase 1 Clinical Trial and a Phase 2 Clinical Trial (a phase 1/2 clinical trial) shall be deemed a Phase 2 Clinical Trial upon the initiation of the Phase 2 Clinical Trial portion or cohort of such Clinical Trial.

1.1.111 **“Phase 3 Clinical Trial”** means a human clinical trial that is prospectively designed to demonstrate statistically whether a Licensed Product is safe and effective for use in humans in a manner sufficient to obtain Regulatory Approval to market such Licensed Product in patients having the disease or condition being studied as described in U.S. 21 C.F.R. § 312.21(c), or an equivalent Clinical Trial required by a Regulatory Authority outside of the United States, in each case, sponsored by Takeda or its Affiliate or Sublicensee. For purposes of this Agreement, a human clinical trial that combines elements of a Phase 2 Clinical Trial and a Phase 3 Clinical Trial (a phase 2/3 clinical trial) shall be deemed a Phase 3 Clinical Trial upon the initiation of the Phase 3 Clinical Trial portion or cohort of such Clinical Trial.

1.1.112 **“Platform Evaluation Subcommittee”** has the meaning set forth in Section 2.1(g).

1.1.113 **“Platform Evaluation Work”** means the research, development and evaluation of the Poseida Technology Platforms conducted by Poseida following the Effective Date and pursuant to the Platform Evaluation Work Plan.

1.1.114 **“Platform Evaluation Work Plan”** means a research and evaluation work plan for the Poseida Technology Platforms set forth on Exhibit 1.1.114, as may be amended from time to time in accordance with this Agreement.

1.1.115 [...\*\*\*...].

1.1.116 [...\*\*\*...].

1.1.117 **“Poseida”** has the meaning set forth in the Preamble.

1.1.118 **“Poseida Arising IP”** has the meaning set forth in Section 7.2(b)(i)(1).

1.1.119 **“Poseida Background IP”** has the meaning set forth in Section 7.2(a)(i). For clarity, Poseida Background IP includes all Poseida Technology Platforms existing either (x) prior to the Effective Date or (y) on or after the Effective Date and independent of this Agreement.

1.1.120 **“Poseida Indemnitee”** has the meaning set forth in Section 11.2.

1.1.121 **“Poseida LNP”** has the meaning set forth in Section 1.1.125.

1.1.122 **“Poseida Patents”** includes any Patent Rights under the Poseida Arising IP, but excluding, for clarity, any Joint Patents.

1.1.123 **“Poseida Payload”** means Poseida’s proprietary (including Covered by Poseida Background IP and not otherwise publicly available) DNA or RNA material, which may include [...\*\*\*...]

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[...\*\*\*...].

1.1.124 “**Poseida Platform Trademarks**” means those trademarks Controlled by Poseida set forth in [Exhibit 1.1.124](#).

1.1.125 “**Poseida Technology Platforms**” means, as of the Effective Date or thereafter during the Term, (a) nucleic acid modification technology platforms Controlled by Poseida that are relevant to the applicable Program, including without limitation, (i) gene insertion technologies, such as Super piggyBac (“**SPB**”) and site-specific Super piggyBac (“**ssSPB**”), and (ii) gene editing technologies, such as Cas-CLOVER (“**Cas-CLOVER**”), and (b) proprietary LNP delivery technologies Controlled by Poseida, including any and all LNP delivery compositions (“**Poseida LNP**”), in each case of (a) and (b) as further described on [Exhibit 1.1.125](#), and any improvements thereto.

1.1.126 “**Pre-Existing Affiliates**” has the meaning set forth in [Section 5.7](#).

1.1.127 “**Product Trademark**” means any trademark or service mark for use in connection with the distribution, marketing, promotion and sale of Licensed Products, or accompanying logos, trade dress or indicia of origin, but specifically excluding the corporate names and logos of the Parties and their Related Parties.

1.1.128 “**Program**” means each of the Initial Indication Programs, the Additional Indication Programs and the Further Indication Programs, which, for clarity, shall continue for the Term of this Agreement or until terminated by Takeda.

1.1.129 “**Program Failure**” means, with respect to a given Program, that further progression of such Program is not commercially reasonable due to (a) [...\*\*\*...], (b) [...\*\*\*...], or (c) [...\*\*\*...].

1.1.130 “**Program Subcommittee**” has the meaning set forth in [Section 2.1\(h\)](#).

1.1.131 “**Public Domain Payload**” means DNA or RNA material that is either wild-type or otherwise entirely in the public domain, including with respect to components of such DNA or RNA material and configuration thereof, where such DNA or RNA material comprises[...\*\*\*...].

1.1.132 “**Receiving Party**” has the meaning set forth in [Section 8.1\(a\)](#).

1.1.133 “**Regulatory Approval**” means the approvals, licenses, registrations or authorizations of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product for a particular Indication in a country, including separate pricing or reimbursement approvals that may be required or desirable in a given jurisdiction.

1.1.134 “**Regulatory Authority**” means the federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, manufacture, use, storage, import, promotion, marketing or sale of a Licensed Product in a country or jurisdiction.

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- 1.1.135 “**Related Party**” means, with respect to a Party, such Party’s Affiliates and permitted Sublicensees.
- 1.1.136 “[...\*\*\*...]” has the meaning set forth in [Section 3.3\(a\)\(ii\)](#).
- 1.1.137 “**Research Activities**” means the activities to be conducted by the Parties in support of the Collaboration, as set forth in the Research Plans.
- 1.1.138 “**Research Costs**” means all reasonable and documented costs, including the FTE Costs incurred, and the Out-of-Pocket Costs recorded as an expense in accordance with the Applicable Accounting Standards, incurred by Poseida that are reasonably identifiable or allocable to its activities under a given Program consistent with the applicable Research Plan, including, for the avoidance of doubt, [...\*\*\*...].
- 1.1.139 “**Research Costs Cap**” means, with respect to each Program, the budget amount specified in the Research Plan for such Program, and excess amounts to the extent such amounts do not exceed [...\*\*\*...] of the total amounts to be incurred under the applicable Research Plan; *provided, however* that additional excess amounts may, subject to the unanimous approval of the JSC, be included in Research Costs if such additional excess amounts were caused by circumstances not within the reasonable control of Poseida.
- 1.1.140 “**Research Period**” means (a) with respect to the Initial Indication Programs, the period from the Effective Date until Candidate Selection or (b) with respect to the Additional Indication Programs and the Further Indication Programs, from Takeda’s exercise of the relevant License Option until Candidate Selection, in each case of (a) and (b), unless extended by mutual agreement of the Parties.
- 1.1.141 “**Research Plan**” means a research plan setting forth in reasonable detail the work projects, Indication, scientific objectives and criteria, Research Activities with respect to a Program, timeframe for such Research Activities, and related budget, as such may be reviewed and amended by the JSC from time to time pursuant to [Section 2.1\(d\)\(iii\)](#). The initial Research Plans for each of the Initial Indication Programs as of the Effective Date are attached hereto as [Exhibit 1.1.141A](#) and [Exhibit 1.1.141B](#), respectively.
- 1.1.142 “**Reversion IP**” has the meaning set forth in [Section 10.5\(b\)\(i\)\(1\)](#).
- 1.1.143 “**Reversion Products**” has the meaning set forth in [Section 10.5\(b\)\(i\)\(1\)](#).
- 1.1.144 “**Royalty Term**” has the meaning set forth in [Section 6.6\(b\)](#).
- 1.1.145 “**Safety Concern**” means, with respect to any Licensed Product, (a) [...\*\*\*...] or (b) [...\*\*\*...].
- 1.1.146 “**Selected Candidate**” has the meaning set forth in [Section 1.1.26](#).
- 1.1.147 “**SPB**” has the meaning set forth in [Section 1.1.125](#).

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1.1.148 “**ssSPB**” has the meaning set forth in Section 1.1.125.

1.1.149 “**Step-In Right**” has the meaning set forth in Section 10.4.

1.1.150 “**Sublicensee**” means a Third Party to whom Poseida has granted or grants rights to conduct Research Activities, or to whom Takeda has granted or grants rights to conduct any activities of Takeda pursuant to this Agreement or to otherwise Exploit any Licensed Product, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights), in each case, in accordance with Sections 5.2(a), 5.2(b), and 5.2(c).

1.1.151 “**Takeda**” has the meaning set forth in the Preamble.

1.1.152 “**Takeda Arising IP**” has the meaning set forth in Section 7.2(b)(ii)(1).

1.1.153 “**Takeda Background IP**” has the meaning set forth in Section 7.2(a)(ii). For clarity, Takeda Background IP includes Takeda Payload and Takeda Materials.

1.1.154 “**Takeda Indemnitee**” has the meaning set forth in Section 11.1.

1.1.155 “**Takeda Materials**” means the Takeda Payload or other materials or research tools, [...\*\*\*...], which Takeda may provide to Poseida for use in connection with the Platform Evaluation Work Plan or a Research Plan.

1.1.156 “**Takeda Patents**” includes any Patent Rights under the Takeda Arising IP, but excluding, for clarity, any Joint Patents.

1.1.157 “**Takeda Payload**” means Takeda’s proprietary (including covered by Takeda Background IP and not otherwise publicly available) DNA or RNA material, which may include [...\*\*\*...].

1.1.158 “**Tax**” or “**Taxes**” means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official in the Territory.

1.1.159 “**Term**” has the meaning set forth in Section 10.1.

1.1.160 “**Territory**” means worldwide.

1.1.161 “**Third Party**” means any Person other than Poseida or Takeda and their respective Affiliates.

1.1.162 “**Third Party Claim**” means any claim, demand, action or other proceeding by any Third Party.

1.1.163 “**Third Party Infringement**” has the meaning set forth in Section 7.6(a).

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- 1.1.164 “[...\*\*\*...] **Indication Exclusivity Period**” means from the Effective Date until [...\*\*\*...].
- 1.1.165 “[...\*\*\*...] **Indications**” means the indications listed on Exhibit 1.1.165.
- 1.1.166 “[...\*\*\*...] **Indications**” means the indications listed on Exhibit 1.1.166.
- 1.1.167 “**United States**” or “**U.S.**” means the United States of America and its territories and possessions.

1.1.168 “**Valid Claim**” means (a) a composition of matter claim or method of use in an issued and unexpired Licensed Patent Right to the extent such claim has not expired or irretrievably lapsed or been abandoned, dedicated to the public, revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final order, from which no further appeal can be taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise or (b) a pending application for a Licensed Patent Rights that (i) has been pending for less than [...\*\*\*...] from [...\*\*\*...] and (ii) has not been finally cancelled, withdrawn, abandoned or rejected by an administration agency action from which no appeal can be taken.

1.1.169 “**VAT**” means, within the European Union, such Tax as may be charged in accordance with (but subject to derogations from) Directive 2006/112/EC and, outside the European Union, value added Tax or any form of consumption Tax, as well as all other forms of Taxes charged on the supply of a good or a service, including sales Tax and goods and services Tax.

## ARTICLE II

### GOVERNANCE

#### 2.1 Joint Steering Committee.

(a) Formation. Within [...\*\*\*...] after the Effective Date, the Parties shall establish a joint steering committee (the “**JSC**”) that shall oversee the activities of the Parties under the Collaboration. The JSC shall be comprised of at least [...\*\*\*...] representatives from each Party. Each Party’s JSC representatives shall have appropriate technical credentials, experience, knowledge, and authority within such Party’s organization for service on the JSC in light of the functions, responsibilities and authority of the JSC. Each Party may replace any or all its representatives on the JSC with individual(s) of appropriate credentials, experience, knowledge and authority at any time upon written notice to the other Party. Additional representatives or consultants of a Party may from time to time, by mutual consent of the Parties, be invited to attend JSC meetings; *provided* that such representatives and consultants are subject to written confidentiality and non-use obligations no less stringent than the requirements of ARTICLE VIII.

(b) JSC Chairperson. The JSC shall be co-chaired, with one chairperson designated by Poseida and one chairperson designated by Takeda, whose responsibilities shall include conducting meetings, including, when feasible, ensuring that objectives for each meeting

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are set and achieved. Responsibility for running each meeting of the JSC will alternate between the co-chairpersons from meeting-to-meeting, with Poseida's chairperson running the first meeting.

(c) Meetings. The JSC shall meet in person or by teleconference at least [...\*\*\*...], or more frequently as Poseida and Takeda deem appropriate or as reasonably requested by either Party, on such dates and at such times as the Parties shall agree; *provided* that the Parties shall endeavor to have the first meeting of the JSC within [...\*\*\*...] after its formation. Meetings of the JSC, when conducted in person, shall alternate between the offices of Poseida and Takeda, or such other places as the Parties may agree. The members of the JSC also may convene or be consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate. At least [...\*\*\*...] from each Party must be present at a meeting of the JSC to have a quorum.

(d) JSC Responsibilities. The JSC shall have the following responsibilities with respect to the Collaboration:

- (i) monitoring, reviewing, discussing and coordinating the overall progress of the Parties under the Collaboration;
- (ii) monitoring, reviewing, discussing and coordinating the overall progress of the Parties under the Platform Evaluation Work Plan and the Research Plans;
- (iii) reviewing, discussing and preparing any amendments to any Research Plan or the Platform Evaluation Work Plan, including for Takeda to take over responsibility for certain Research Activities prior to Candidate Selection;
- (iv) overseeing the conduct of activities under the Platform Evaluation Work Plan and Research Plans, including receiving and reviewing progress reports, data, and other information provided by the Parties in connection with such plans;
- (v) maintaining a current list of Available Indications;
- (vi) establishing, but not delegating decision making authority to, such additional subcommittees as it deems necessary to achieve the objective and intent of this Agreement;
- (vii) overseeing the JSC's subcommittees, if any, and ensuring effective participation in each such subcommittee's operations by any of its members;
- (viii) determining the occurrence of a Program Failure;
- (ix) addressing any other matters referred to the JSC by the terms of this Agreement;
- (x) attempting to resolve any disputes on matters within the JSC's or any subcommittee's authority on an informal basis and in good faith prior to the initiation of escalation or other formal dispute resolution mechanisms hereunder; and
- (xi) performing such other activities as the Parties agree in writing shall be the responsibility of the JSC.

(e) Appointment of Subcommittees and Project Teams. The JSC shall be empowered to create such subcommittees of itself and project teams as it may deem appropriate or necessary, including a Patent Subcommittee, Platform Evaluation Subcommittee, Program

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Subcommittee and Joint Manufacturing Working Group, each as described further below, among others. Each such subcommittee and project team shall report to the JSC, which shall have authority to approve or reject recommendations or actions proposed thereby, subject to the terms of this Agreement. The provisions of Section 2.1(a) (excluding the first sentence thereof), Section 2.1(b) and Section 2.1(c) shall apply to each subcommittee, *mutatis mutandis*, unless otherwise determined by the JSC.

(f) Patent Subcommittee.

(i) Formation. Within [...\*\*\*...] of the formation of the JSC, the Parties shall establish a subcommittee to manage the overall coordination, communication and oversight of the Parties' activities with respect to the Patent Rights arising under this Agreement (the "**Patent Subcommittee**"). Each Party shall designate [...\*\*\*...] for the Patent Subcommittee, which representative may, but need not be, an employee of such Party. Each representative shall have the appropriate level of experience regarding patent prosecution, maintenance, enforcement, and defense of Patent Rights. Each Party may designate a substitute for its Patent Subcommittee representative if such Party's designated representative is unable to be present at a meeting. From time to time each Party may replace its representative by written notice to the other Party specifying the prior representative and his or her replacement.

(ii) Responsibilities. The Patent Subcommittee's responsibilities shall be to serve as a discussion and information sharing forum with respect to the determination of and filing strategies for Poseida Arising IP and Takeda Arising IP pursuant to Section 7.2(b)(i) and Section 7.2(b)(ii), respectively, and Joint Arising IP pursuant to Section 7.2(b)(iii) and the matters set forth in Section 7.4(d) and Section 7.4(e).

(g) Platform Evaluation Subcommittee. Within [...\*\*\*...] of the formation of the JSC, the Parties shall establish a subcommittee to serve as a discussion and information sharing forum with respect to managing the review and transfer, in accordance with Section 4.4, of material data, reports and other information, including scientific and other know-how, sequences (including nucleic acid and amino acid sequences), assembly procedures, specifications, skills, techniques, procedures and experiences, resulting from the conduct of the Platform Evaluation Work Plan or otherwise necessary or reasonably useful for the conduct of the Research Plans (the "**Platform Evaluation Subcommittee**"). Each Party shall provide the materials and information listed in this Section 2.1(g) to the Platform Evaluation Subcommittee. The Platform Evaluation Subcommittee shall consist of an equal (and agreed upon) number of representatives from each of the Parties. The Platform Evaluation Subcommittee shall meet quarterly, or as otherwise mutually agreed by the Parties. Each Party may designate a substitute for one or more of its Platform Evaluation Subcommittee representatives if one or more of such Party's designated representatives is unable to be present at a meeting. From time to time each Party may replace a representative by written notice to the other Party specifying the prior representative and his or her replacement. The Platform Evaluation Subcommittee shall be subject to the oversight, review and approval of, and shall report to, the JSC.

(h) Program Subcommittee. Within [...\*\*\*...] of the formation of the JSC, the Parties shall establish a subcommittee to manage the overall coordination, communication and oversight of therapeutics developed for a Program (the "**Program Subcommittee**"). The Program Subcommittee shall consist of an equal (and agreed upon) number of representatives from each of the Parties. The Program Subcommittee shall meet quarterly, or as otherwise mutually agreed by the Parties. Each Party may designate a substitute for one or more of its Program Subcommittee representatives if one or more of such Party's designated representatives is unable

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to be present at a meeting. From time to time each Party may replace a representative by written notice to the other Party specifying the prior representative and his or her replacement. The Program Subcommittee shall be subject to the oversight, review and approval of, and shall report to, the JSC.

(i) Joint Manufacturing Working Group. Within [...\*\*\*...] of the formation of the JSC, the Parties shall establish a subcommittee that will be responsible for Manufacturing and supply matters delegated to it by the JSC (the "**Joint Manufacturing Working Group**"). The Joint Manufacturing Working Group shall consist of an equal (and agreed upon) number of representatives from each of the Parties, each with requisite experience and seniority to enable such person to oversee and make decisions regarding CMC activities and matters under this Agreement. The Joint Manufacturing Working Group shall meet monthly, or as otherwise mutually agreed by the Parties. Each Party may designate a substitute for one or more of its Joint Manufacturing Working Group representatives if one or more of such Party's designated representatives is unable to be present at a meeting. From time to time each Party may replace a representative by written notice to the other Party specifying the prior representative and his or her replacement. The Joint Manufacturing Working Group shall be subject to the oversight, review and approval of, and shall report to, the JSC.

(j) Decision-Making Authority.

(i) Subject to the remainder of this Section 2.1(j), all decisions of the JSC shall be made by consensus, with each Party's JSC representatives collectively having [...\*\*\*...].

(ii) If the JSC is unable to reach a consensus with respect to a dispute within [...\*\*\*...], then the dispute shall be submitted to the Executive Officers of Poseida and Takeda for resolution, who shall promptly initiate discussions in good faith to resolve such dispute.

(iii) If such escalated dispute cannot be resolved within [...\*\*\*...] of the dispute being submitted to the Executive Officers, then subject to clause (iv) below, (A) [...\*\*\*...].

(iv) [...\*\*\*...].

(v) Upon [...\*\*\*...] prior written notice, either Party may convene a special meeting of the JSC for the purpose of resolving any failure to reach agreement on a matter within the scope of the authority and responsibility of the JSC.

(k) Dissolution of JSC. With respect to each Program, the JSC's responsibilities, and the responsibilities of any subcommittee under the JSC, shall terminate automatically upon [...\*\*\*...]

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[...\*\*\*...]. Thereafter, each Party shall designate, to the extent necessary, a contact person for the exchange of information under this Agreement or such exchange of information shall be made through the Alliance Managers, and decisions of the JSC, if any, shall be decisions as between the Parties, subject to the other terms and conditions of this Agreement.

2.2 Limitation on JSC Authority. The JSC shall conduct its activities in good faith and shall not have the power to (a) amend or modify the Parties' respective rights and obligations under this Agreement, (b) waive either Party's compliance with the terms and conditions of this Agreement, (c) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement, (d) resolve any dispute between the Parties regarding such rights and obligations or (e) require the other Party to violate any applicable Law, ethical requirement or any agreement it may have with any Third Party. For clarity, [...\*\*\*...] shall have the sole authority and discretion for Candidate Selection with respect to a Program.

2.3 Expenses. Each Party shall be responsible for all costs and expenses for its members and other representatives to attend meetings of, and otherwise participate in, the JSC and any subcommittees and project teams, including all travel and related costs and expenses.

2.4 Alliance Managers.

(a) Each Party shall appoint an alliance manager who is an employee of such Party (each, an "**Alliance Manager**"). Each Alliance Manager shall be responsible to ensure a collaborative work environment between the Parties and that the Collaboration is run smoothly, professionally and productively. Each Alliance Manager shall act in his or her discretion to facilitate the execution of the Collaboration throughout their organization and will (i) oversee and support implementation plans, (ii) promote effectiveness of the governance model and implementation of contractual provisions and lead any changes to enhance the Collaboration, (iii) facilitate the JSC and any subcommittees and project teams for effective decision making in a timely manner, and (iv) undertake such other tasks as are detailed in this Agreement or as may be assigned by the JSC. Each Alliance Manager will serve as the primary point of contact for the other Party under the Collaboration. Each Alliance Manager shall attend each meeting of the JSC. Each Party may change its Alliance Manager at any time in its sole discretion with written notice to the other Party.

(b) The Alliance Managers shall be responsible for (i) scheduling meetings of the JSC and subcommittees, (ii) setting agendas for JSC and subcommittee meetings with solicited input from the co-chairs and other members and (iii) for acting as secretary at each such meeting and preparing the draft minutes of such meeting, which shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JSC or subcommittee. Within [...\*\*\*...] after each such meeting, the drafting Alliance Manager shall provide the draft minutes to the other Alliance Manager for review and comment. The drafting Alliance Manager shall reasonably consider all comments from the other Alliance Manager that are provided within [...\*\*\*...]. The drafting Alliance Manager shall prepare and submit revised minutes for approval within [...\*\*\*...] after receipt of such comments or upon the expiration of such [...\*\*\*...] comment period. Beginning with Poseida's Alliance Manager, such responsibilities shall alternate between the Alliance Managers on a meeting-by-meeting basis after each meeting of the JSC or subcommittee, as applicable.

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ARTICLE III

COLLABORATION

3.1 Platform Evaluation Work Plan and Activities.

(a) Initial Platform Evaluation Work Activities. Poseida shall perform the activities set forth in the Platform Evaluation Work Plan, which shall be at its own cost, in accordance with the timelines set forth therein, including all activities required to complete engineering and evaluation work and deliver the Final Data Package to Takeda.

(b) Final Data Package. Within [...\*\*\*...] after the completion of the activities under the Platform Evaluation Work Plan, Poseida shall provide Takeda with the Final Data Package (...\*\*\*...). During the [...\*\*\*...] period following delivery to Takeda of the Final Data Package, Takeda shall have the opportunity to review and inspect the Final Data Package and to ask [...\*\*\*...] questions of, or request [...\*\*\*...] additional information from, Poseida and receive [...\*\*\*...] answers or receipt of information from Poseida related thereto. [...\*\*\*...]. Notwithstanding the foregoing, no limitation on additional information or data shall modify the contents required to be in the Final Data Package. Poseida shall use Commercially Reasonable Efforts to provide to Takeda such requested supplemental data or information within [...\*\*\*...] of its receipt of such notice and [...\*\*\*...].

(c) Amendment of the Platform Evaluation Plan. Either Party, directly or through its representatives on the JSC, may propose amendments to the Platform Evaluation Work Plan from time to time, as appropriate, including in light of changed circumstances. Any and all such amendments shall be subject to approval by the JSC as set forth in Section 2.1(d), subject to the decision-making authority of Section 2.1(j).

3.2 Research Plans.

(a) Research Activities. Subject to the terms and conditions of this Agreement, the Parties agree to conduct research and pre-clinical development on a collaborative basis in connection with the Programs as further described below. Each Party will use [...\*\*\*...] to perform its assigned activities as set forth in the Research Plans for each Program during the Research Period in accordance with the timelines specified therein; *provided*

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that, prior to Candidate Selection, Takeda may, in its sole discretion, upon [...] prior written notice to Poseida, [...]; *provided, further*, that, during such [...] period, the Parties [...]. Without limiting the foregoing, each Party will conduct the Research Activities assigned to it under the Research Plans in a good scientific manner and in compliance in all material respects with applicable Law, including applicable national and international (e.g., ICH, GCP, GLP, and GMP) guidelines.

(b) Additional Research Plans and Amendment. Takeda shall be responsible for the preparation, in its sole discretion, and presentation to the JSC for approval, of the Research Plan for any Additional Indication Program or Further Indication Program, *provided* that the FTE requirements shall not be [...]. Either Party, directly or through its representatives on the JSC, may propose amendments to the Research Plans from time to time, as appropriate, including in light of changed circumstances. Any and all such Research Plans and amendments to any Research Plan (including with respect to any [...]) shall be subject to approval by the JSC as set forth in Section 2.1(d), subject to the decision-making authority of Section 2.1(j). In the event of any inconsistency between the Research Plans and this Agreement, the terms of this Agreement shall prevail. For clarity, Research Activities under the Research Plans may be conducted in parallel to the Platform Evaluation Work.

(c) Takeda Technology Transfer. Takeda shall make available to Poseida [...], the Takeda Background IP and any other information or materials Controlled by Takeda or any of its Affiliates that in each case is necessary for Poseida to conduct its activities under the Research Plan. Takeda shall make its relevant scientific and technical personnel reasonably available to answer any questions or provide instructions as reasonably requested by Poseida concerning the use and understanding of the items delivered pursuant to this Section 3.2(c).

### 3.3 Research Activities.

#### (a) Initial Indication Programs.

(i) Takeda has initiated and elected to initiate, respectively, [...] programs for the Indications of (A) hemophilia A and (B) [...] (each an “**Initial Indication Program**” and together, the “**Initial Indication Programs**”). Pursuant to the terms of this Agreement and as further provided in this ARTICLE III, each Party shall use Commercially Reasonable Efforts to carry out the activities assigned to it as specified in the applicable Research Plan through Candidate Selection. [...].

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(ii) [...\*\*\*...].

(b) Takeda Option for Additional Programs.

(i) Additional Indication Programs. Takeda shall have the right to select Indications, in accordance with Section 3.3(c), for up to four (4) additional programs (each an “**Additional Indication Program**”) at any time not later than [...\*\*\*...], as such period may be extended pursuant to Section 3.1(b) (the “**Additional Indication Option Period**”). Takeda shall have the right to exercise its option (the “**Additional Indication License Option**”) by providing written notice of such election to Poseida (“**Additional Indication Program Notice**”) at any time after the Effective Date and prior to the end of the Additional Indication Option Period. Upon exercising the Additional Indication License Option and Poseida’s receipt of the Additional Indication Program Notice, Takeda shall be deemed to have entered into the license set forth in Section 5.2(c). [...\*\*\*...].

(ii) Further Indication Programs. Takeda shall have the right to select Indications, in accordance with Section 3.3(c), for up to two (2) further Programs (each a “**Further Indication Program**”) at any time not later than [...\*\*\*...], as such period may be extended pursuant to Section 3.1(b) (the “**Further Indication Option Period**”). Takeda shall have the right to exercise its option (the “**Further Indication License Option**”) by providing written notice of such election to Poseida (“**Further Indication Program Notice**”) at any time after the Effective Date and prior to the end of the Further Indication Option Period. Upon exercising the Further Indication License Option and Poseida’s receipt of the Further Indication Program Notice, Takeda shall be deemed to have entered into the license set forth in Section 5.2(c). [...\*\*\*...].

(iii) Diligence. Pursuant to the terms of this Agreement and as further provided in this ARTICLE III, each Party shall use [...\*\*\*...] to carry out the activities assigned to it as specified in the applicable Research Plan for any Additional Indication Program and Further Indication Program.

[...\*\*\*...]

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[...\*\*\*...]

(c) Indication Availability.

(i) [...\*\*\*...] Indications. Takeda may select a [...\*\*\*...] Indication for use in an Additional Indication Program, Further Indication Program or as a [...\*\*\*...] at any time during the [...\*\*\*...] Indication Exclusivity Period. Following the [...\*\*\*...] Indication Exclusivity Period, with respect to the Additional Indication Programs and Further Indication Programs, Takeda shall still have the right to [...\*\*\*...].

(ii) [...\*\*\*...] Indications. Takeda may select a [...\*\*\*...] Indication as a [...\*\*\*...] or as the Indication for an Additional Indication Program or Further Indication Program, in each case, subject to Availability.

3.4 Research Costs.

(a) Within [...\*\*\*...] after the end of each Calendar Quarter of the Research Plans, Poseida shall invoice Takeda for the Research Costs incurred by Poseida in connection with the performance of activities under the Research Plans, in accordance with the budgets set forth therein, during such Calendar Quarter and in accordance with the Research Plans, and Takeda shall pay each invoice in accordance with Section 6.11 within [...\*\*\*...] of receipt of such invoice. Notwithstanding the foregoing, if cumulative Research Costs with respect to any Research Plan exceed the applicable Research Costs Cap, as adjusted pursuant to Section 1.1.139 (the "Excess Cost"), then [...\*\*\*...].

(b) Except as expressly set forth in this Agreement and subject to Section 6.6(c)(ii), as between the Parties, [...\*\*\*...] shall be solely responsible for any obligations, financial or otherwise, owed by [...\*\*\*...] or its Affiliates to Third Parties, including with respect to any Intellectual Property rights licensed to [...\*\*\*...] by such Third Parties.

(c) Takeda shall be responsible for all costs incurred by Takeda in performing the Research Activities pursuant to the Research Plans.

3.5 Records.

Each Party will maintain scientific records, accounts, notes, reports and data with respect to its Research Activities, in accordance with applicable Law and standard pharmaceutical industry practices and in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which will fully and properly reflect all work done and results achieved in the performance of the Research Activities by such Party under the Research Plans; *provided* that in no case shall such records be maintained for less than [...\*\*\*...] following the Calendar Year to which such records pertain or such longer period as required by applicable Law or any In-License Agreement [...\*\*\*...]. Upon the other Party's written request, the Party receiving such written request shall send legible copies of the aforesaid to the other Party throughout the Term and for a minimum of [...\*\*\*...] following such Term. In accordance with (a) the reporting format and schedule approved by the JSC, each Party shall promptly disclose to the other Party in writing any material data, including material pre-clinical data, formulation data and manufacturing data, generated by or on behalf of such Party under the Collaboration, and (b) any reporting format and schedule established by the Parties after Candidate Selection, [...\*\*\*...].

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3.6 Materials Transfer.

In order to facilitate the activities contemplated under the Platform Evaluation Work Plan or Research Plans, either Party may provide to the other Party certain biological materials technologies, including, with respect to Takeda, the Takeda Materials (collectively, "**Materials**") for use by the other Party in furtherance of the Platform Evaluation Work Plan or Research Plans. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the activities conducted in accordance with the Platform Evaluation Work Plan or Research Plans, will not be used or delivered to or for the benefit of any Third Party (except for subcontractors permitted under this Agreement in furtherance of the Research Plans), without the prior written consent of the supplying Party, and will be used in compliance with applicable Law. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. The supplying Party will provide the other Party the most current material safety data sheet for the Materials upon transfer of any Materials. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY. At either Party's request, the Parties shall enter into a materials transfer agreement to govern the transfer of Materials between the Parties.

3.7 Adverse Event Reporting.

Each Party shall be responsible for the monitoring and reporting of safety information, if any, generated in the conduct of its Research Activities and will promptly report such information to the other Party.

3.8 Regulatory Matters.

Until Candidate Selection for a particular Program, (a) Poseida shall provide reasonable assistance to Takeda, at Takeda's reasonable request [...\*\*\*...], with respect to any activities related to Regulatory Approval of any Licensed Product, and (b) Takeda shall provide reasonable assistance to Poseida at Poseida's reasonable request [...\*\*\*...] with respect to any activities related to Regulatory Approval of any Poseida Technology Platform or Reversion Product, including any filing, application or submission to any Regulatory Authority, including, in each of clauses (a) and (b), any filing, application or submission to any Regulatory Authority. Following Candidate Selection, Poseida shall provide reasonable assistance to Takeda, at Takeda's reasonable request and at no additional cost to Takeda for up to [...\*\*\*...] per year with respect to any activities related to Regulatory Approval of any Licensed Product; [...\*\*\*...].

3.9 Third Parties.

Takeda shall be entitled to utilize the services of Third Party contract research organizations to perform its activities under the Research Plans and this ARTICLE III. Unless agreed in a Research Plan, Poseida may not engage a subcontractor to conduct any Research Activities without Takeda's prior written consent. Poseida shall be entitled to engage subcontractors to conduct its activities under the Platform Evaluation Work Plan, without Takeda's prior written consent.

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## ARTICLE IV

### DEVELOPMENT, MANUFACTURE, COMMERCIALIZATION AND REGULATORY MATTERS

#### 4.1 Responsibility for Development and Commercialization.

Following Candidate Selection with respect to a Program, Takeda shall be solely responsible, at its sole cost and expense, for all activities related to the Development and Commercialization of the Licensed Products under such Program and Poseida shall have no right or obligation (including research obligations) to Exploit any such Licensed Products; *provided* that upon mutual agreement of the Parties, Poseida may perform further research activities with respect to such Program.

#### 4.2 Diligence.

Following Candidate Selection with respect to a Program, Takeda shall use Commercially Reasonable Efforts to Develop and, following Regulatory Approval, Commercialize [...\*\*\*...].

#### 4.3 Regulatory Matters.

At all times during the Term, Takeda shall be responsible for obtaining Regulatory Approval with respect to the Licensed Products, communicating with Regulatory Authorities and otherwise carrying out regulatory activities as set forth in this Agreement. Takeda shall own the INDs, BLAs and related regulatory documents submitted to the applicable Regulatory Authorities by it with respect to the Licensed Products and shall (a) oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, each Regulatory Authority, (b) be responsible for interfacing, corresponding and meeting with each Regulatory Authority, and (c) be responsible for maintaining all regulatory filings. In the event Poseida receives a communication from any Regulatory Authority related to any Licensed Product, Poseida will provide Takeda with a copy of such communication within [...\*\*\*...] of Poseida's receipt thereof and will reasonably assist Takeda in responding to such communication, *provided*, for clarity, that Takeda will be the lead in such response.

#### 4.4 Know-How and Technology Transfer.

(a) Following Candidate Selection with respect to a Program and at no additional cost to Takeda except as set forth in Section 4.4(c), the Parties shall perform a technology transfer as follows:

(i) Poseida shall make available to Takeda, in a format specified by Takeda (and reasonably acceptable to Poseida), the following items then in existence: [...\*\*\*...] (the "**Initial Technology Transfer**"). Poseida shall make its relevant scientific and technical personnel reasonably available to answer any questions or provide instructions as reasonably requested by Takeda concerning the use and understanding of the items delivered pursuant to this Section 4.4(a)(i). The Parties shall use [...\*\*\*...] to ensure that the Initial Technology Transfer is efficient and occurs in a reasonably timely manner.

(ii) [...\*\*\*...].

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(b) Following the Initial Technology Transfer, Takeda shall have the right, at any time and from time to time through Regulatory Approval, to require Poseida to effect a full transfer to Takeda or its designee (which designee may be an Affiliate or a Third Party manufacturer or CMO) of [...\*\*\*...] (each such transfer, an “**Additional Technology Transfer**”). In furtherance of each Additional Technology Transfer, Poseida shall, and shall use Commercially Reasonable Efforts to cause its CMOs to, [...\*\*\*...]

(c) Poseida shall provide up to [...\*\*\*...] in support of Poseida’s activities under Section 4.4(b); *provided*, that any FTEs in excess of [...\*\*\*...] shall be at Takeda’s sole cost and expense and Poseida shall invoice Takeda for its costs (including FTE Costs at the FTE Rate) incurred in connection therewith on a quarterly basis. For clarity, the [...\*\*\*...] provided by Poseida under this Section 4.4(c), are separate and in addition to the [...\*\*\*...] provided by Poseida under Section 3.8.

4.5 Manufacture by CMO.

(a) Unless otherwise agreed by the Parties, if Poseida is performing any Manufacturing activities that are specific to [...\*\*\*...], through one or more CMOs, then, in connection with the Initial Technology Transfer to Takeda, the Parties will discuss in good faith the assignment or transfer or sublicense to Takeda, to the extent practicable, of the agreements between Poseida and one or more of such CMOs, to the extent such agreements [...\*\*\*...].

(b) As of the Effective Date, with respect to any agreement that Poseida enters into with a CMO to supply Licensed Products (each such agreement, a “**CMO Agreement**”), Poseida shall use Commercially Reasonable Efforts to provide that such CMO Agreement provides that [...\*\*\*...].

(c) Notwithstanding anything in this Agreement to the contrary, except as otherwise agreed by the Parties and except for [...\*\*\*...]

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[...\*\*\*...].

4.6 Cooperation.

At Takeda's reasonable request and expense (and not, for the avoidance of doubt, subject to the Research Cost Cap), and [...\*\*\*...], after Candidate Selection with respect to a Program, Poseida will cooperate with Takeda in the conduct of the Development of the Licensed Products, including providing Takeda with technical assistance and regulatory-related support on an as-needed basis.

4.7 Third Parties.

Takeda shall be entitled to utilize the services of Third Parties to perform its Development, Manufacturing and Commercialization activities under this ARTICLE IV or to otherwise Exploit the Licensed Products; *provided* that it shall comply with Section 5.2(d).

**ARTICLE V**

**GRANT OF LICENSE RIGHTS**

5.1 Poseida Technology Platforms.

(a) Poseida Technology Platform [...\*\*\*...]. Takeda shall have the right, in its sole discretion [...\*\*\*...], to [...\*\*\*...], as may be described in the Final Data Package at any time not later than (i) [...\*\*\*...], or (ii) [...\*\*\*...], in each case of (i) and (ii) upon written notice to Poseida [...\*\*\*...]; *provided*, that, in the event of [...\*\*\*...], such period limitation shall not apply and Takeda shall have the right to [...\*\*\*...]. For clarity, [...\*\*\*...].

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(b) Future Poseida Technology Platforms. To the extent Takeda uses, in connection with a Licensed Product, [...\*\*\*...], pursuant to an In-License Agreement entered into after the Effective Date, [...\*\*\*...].

## 5.2 License Grants to Takeda.

(a) Research License. Subject to the terms and conditions of this Agreement, Poseida hereby grants to Takeda a non-exclusive, royalty-free, worldwide, sublicensable (solely to its Affiliates and Third Parties who engage in research activities in collaboration with, or as a fee-for-service for, Takeda or any of its Affiliates) license under the Licensed IP to perform Takeda's obligations under the Platform Evaluation Work Plan and Research Plans (including any additional activities assumed by Takeda pursuant to Section 3.2(a)).

(b) Initial Indication Programs. Subject to the terms and conditions of this Agreement, with respect to each Initial Indication Program, Poseida hereby grants to Takeda an exclusive, royalty-bearing license, with the right to grant sublicenses to Affiliates and Third Parties (through multiple tiers), under the Licensed IP and Poseida's interest in the Joint Arising IP, to Exploit any and all Selected Candidates and Licensed Products under such Initial Indication Program in the Territory in the Field.

(c) Additional Indication Programs and Further Indication Programs. Subject to the terms and conditions of this Agreement (including Section 3.3(b)(i) and Section 3.3(b)(ii)), with respect to each Additional Indication Program or Further Indication Program and effective as of the exercise by Takeda of the applicable Additional Indication License Option or Further Indication License Option, Poseida hereby grants to Takeda an exclusive, royalty-bearing license, with the right to grant sublicenses to Affiliates and Third Parties (through multiple tiers), under the Licensed IP and Poseida's interest in the Joint Arising IP to Exploit any and all Selected Candidates and Licensed Products under such Additional Indication Program or Further Indication Program in the Territory in the Field.

### (d) Sublicensing Terms.

(i) Takeda shall have the right to sublicense (through multiple tiers) any of its rights under Section 5.2(b) or Section 5.2(c) to any Affiliate of Takeda or any Third Party, *provided* that any such sublicense shall comply with the applicable terms of this Agreement. As soon as reasonably practicable (but in any event within [...\*\*\*...]) following the grant of any such sublicenses, other than non-exclusive sublicenses in the normal course of business that do not grant commercialization rights to the Sublicensee or sublicenses to Affiliates, Takeda shall notify Poseida of the grant of such sublicense and provide to Poseida a copy of the applicable sublicense agreement, which copy may be redacted with respect to information not pertinent to compliance with this Agreement.

(ii) Notwithstanding any sublicense, Takeda shall remain primarily liable to Poseida for the performance of all of Takeda's obligations under, and Takeda's compliance with all terms and conditions of, this Agreement, including all obligations delegated to its Sublicensees.

(e) Retained Rights. Poseida shall retain rights under the licenses granted to Takeda in this Section 5.2 solely to the extent necessary to conduct its Research Activities under the Research Plans.

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(f) Limitations. Notwithstanding anything to contrary herein, the foregoing licenses do not include the grant of any rights under the Licensed IP or Poseida's interest in the Joint Arising IP for purposes of [...\*\*\*...]. For clarity, [...\*\*\*...].

(g) In-License Agreements.

(i) The terms of this Agreement, including the licenses and rights granted to Takeda hereunder, are subject in all respects to terms of the In-License Agreements [...\*\*\*...] and Takeda shall comply with such terms.

(ii) To the extent such information is not the Confidential Information of Takeda, Poseida shall have the right to incorporate information received from Takeda at the JSC or otherwise under this Agreement as needed to fulfill its reporting obligations under any In-License Agreements. If Poseida reasonably believes that it requires any additional information from Takeda to comply with its reporting obligations under any In-License Agreements, then Poseida shall specify in writing to Takeda such information so required and Takeda shall provide Poseida such information within Takeda's Control in a timely manner so as to enable Poseida to comply with such reporting requirements; *provided* that if such information is Confidential Information of Takeda and Takeda objects to providing any such Confidential Information to such Third Party, the Parties shall [...\*\*\*...] (A) [...\*\*\*...], or (B) [...\*\*\*...]. In no event will the failure by Poseida to comply with such reporting requirement under an In-License Agreement, if due solely to any failure by Takeda to provide Poseida such information in a timely manner, be deemed a breach by Poseida of such In-License Agreement for purposes of this Agreement or create any liability of Poseida to Takeda therefor.

(iii) Notwithstanding anything to the contrary herein, subject to the remainder of this Section 5.2(g)(iii), Poseida grants to Takeda no rights or licenses under the Excluded In-License Agreements; *provided* that, if at any time during the Term, [...\*\*\*...]. For clarity, the Parties agree that as of the Effective Date, no activities are planned under this Agreement that would require the inclusion of any Excluded In-License.

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5.3 License Grant to Poseida. Subject to the terms and conditions of this Agreement, during the Research Period, Takeda hereby grants to Poseida a non-exclusive, worldwide license under the Takeda Background IP (to the extent made available from Takeda to Poseida in connection with this Agreement), Takeda Arising IP and Takeda's interest in the Joint Arising IP to conduct its Research Activities under the Research Plan. For clarity, Poseida may subcontract its rights under this Section 5.3 in connection with the completion of Research Activities under a Research Plan.

5.4 Exclusivity.

(a) Poseida and its Affiliates shall not (i) work with any Third Party to use the [...\*\*\*...], or (ii) grant any rights or enter into negotiations with a Third Party for the purpose of granting any right or license under, or any covenant to not sue with respect to, [...\*\*\*...].

(b) From the Effective Date through the [...\*\*\*...] Indication Exclusivity Period, Poseida will not, nor will it authorize, permit or enable any of its Affiliates or any Third Party to, conduct, directly or indirectly, [...\*\*\*...].

(c) From the Effective Date with respect to the Initial Indication Programs, and following Takeda's selection of an Indication as [...\*\*\*...] or for an Additional Indication Program or Further Indication Program, Poseida will not, nor will it authorize, permit or enable any of its Affiliates or any Third Party to, [...\*\*\*...].

(d) During the Term, Takeda shall not, nor shall it authorize, permit or enable any of its Affiliates or any Third Party to, [...\*\*\*...].

(e) This Section 5.4 shall not limit any activities of an Acquirer of Poseida (or such Acquirer's pre-existing Affiliates) for which Poseida or such Acquirer institute commercially reasonable technical and administrative safeguards, including by [...\*\*\*...]. Notwithstanding anything herein to the contrary, this Section 5.4 shall cease to apply with respect to each Indication upon termination of the applicable Program or, in the case of an Initial Indication, [...\*\*\*...]; provided that this Section 5.4 shall continue to apply to any such Indication for as long as such Indication is the subject of any other active Program.

5.5 Section 365(n) of the Bankruptcy Code.

All rights and licenses granted under or pursuant to this Agreement by a Party to the other Party, including those set forth in Section 5.2

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and Section 5.3, are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties and their respective Related Parties, as Sublicensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterpart thereto. The Parties further agree that upon commencement of a bankruptcy proceeding by or against a Party (the “**Bankrupt Party**”) under the U.S. Bankruptcy Code, the other Party (the “**Non-Bankrupt Party**”) will be entitled to a complete duplicate of, or complete access to (as the Non-Bankrupt Party deems appropriate), all such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments of such intellectual property will be promptly delivered to the Non-Bankrupt Party (a) upon any such commencement of a bankruptcy proceeding and upon written request by the Non-Bankrupt Party, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Bankrupt Party and upon written request by the Non-Bankrupt Party. The Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) agrees not to interfere with the exercise by the Non-Bankrupt Party or its Related Parties of its rights and licenses to such intellectual property and such embodiments of intellectual property in accordance with this Agreement, and agrees to assist the Non-Bankrupt Party and its Related Parties in obtaining such intellectual property and such embodiments of intellectual property in the possession or control of Third Parties as reasonably necessary or desirable for the Non-Bankrupt Party to exercise such rights and licenses in accordance with this Agreement. The foregoing provisions are without prejudice to any rights the Non-Bankrupt Party may have arising under the U.S. Bankruptcy Code or other Laws.

5.6 No Other Rights.

Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest or other right in any Know-How, Patent Rights or other Intellectual Property rights of the other Party, including items owned, controlled or developed by the other Party, or provided by the other Party to the receiving Party at any time pursuant to this Agreement.

5.7 Change of Control.

(a) Notwithstanding anything in this Agreement to the contrary, following the closing of a Change of Control of a Party (the “**Acquired Party**”), the Parties agree that [...\*\*\*...]

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[...\*\*\*...].

(b) [...\*\*\*...].

## ARTICLE VI

### FINANCIAL PROVISIONS

#### 6.1 Upfront Payment and Initial Research Funding.

As partial consideration for the exclusive rights and covenants granted by Poseida to Takeda pursuant to this Agreement, within [...\*\*\*...] after receipt of a valid invoice from Poseida promptly issued following the Effective Date, Takeda shall make to Poseida (a) a one-time non-refundable, non-creditable up-front payment of forty million Dollars (\$40,000,000) and (b) a one-time non-refundable, non-creditable payment of five million Dollars (\$5,000,000) to fund research for the Initial Indication Programs.

#### 6.2 Option Exercise Payment.

(a) Additional Indication Programs. As partial consideration for the exclusive rights and covenants granted by Poseida to Takeda pursuant to this Agreement, within [...\*\*\*...] after Takeda's selection of an Indication for an Additional Indication Program, Takeda shall make to Poseida a one-time non-refundable, non-creditable payment of [...\*\*\*...] for each such Additional Indication Program. In no event will the total amount of option exercise payments for the Additional Indication Programs exceed [...\*\*\*...].

(b) Further Indication Programs. As partial consideration for the exclusive rights and covenants granted by Poseida to Takeda pursuant to this Agreement, within [...\*\*\*...] after Takeda's selection of an Indication for a Further Indication Program, Takeda shall make to Poseida a one-time non-refundable, non-creditable payment of [...\*\*\*...] for each such Further Indication Program. In no event will the total amount of option

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exercise payments for the Further Indication Programs exceed [...\*\*\*...].

For clarity, no such payment shall be made in connection with either Initial Indication Program (or [...\*\*\*...]) or in connection with [...\*\*\*...].

6.3 Research and Pre-Clinical Milestones.

As partial consideration for the exclusive rights and covenants granted by Poseida to Takeda pursuant to this Agreement, Takeda shall make to Poseida non-refundable, non-creditable milestone payments (each, a “**Research and Pre-Clinical Milestone Payment**”) on a Program-by-Program basis upon achievement of the milestones set forth below. Takeda will notify Poseida of the achievement of each such milestone no later than [...\*\*\*...] after Takeda becoming aware of the achievement thereof. Thereafter, Poseida will provide Takeda with an invoice for the corresponding Research and Pre-Clinical Milestone Payment, and Takeda shall pay each Research and Pre-Clinical Milestone Payment within [...\*\*\*...] after receipt of such invoice.

<u>Milestone Event</u>	<u>Milestone Payment</u>
[...***...]	
[...***...]	[...***...]
[...***...]	[...***...]
[...***...]	
[...***...]	[...***...]
[...***...]	[...***...]
[...***...]	[...***...]

Each Research and Pre-Clinical Milestone Payment set forth above shall be payable only once for the first occurrence of the specified milestone event for each Program, as applicable, regardless of the number of Licensed Products that achieve the applicable milestone event with respect to such Program, and in no event will the Research and Pre-Clinical Milestone Payments set forth in this Section 6.3 exceed [...\*\*\*...] in the aggregate across the Initial Indication Programs and the Additional Indication Programs. For clarity, if a Research and Pre-Clinical Milestone Payment is made with respect to a milestone event for a Program and subsequently there is a [...\*\*\*...], then the achievement of such milestone event with respect to such [...\*\*\*...] or [...\*\*\*...] shall not trigger another Research and Pre-Clinical Milestone Payment. If the [...\*\*\*...] milestone for any Program is achieved before achievement of the preceding milestone for such Program (i.e., [...\*\*\*...])

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[...\*\*\*...], [...\*\*\*...].

6.4 Development and Regulatory Milestones. As partial consideration for the exclusive rights and covenants granted by Poseida to Takeda pursuant to this Agreement, Takeda shall make non-refundable, non-creditable milestone payments (each, a “**Development and Regulatory Milestone Payment**”) to Poseida upon achievement of the milestones set forth below (each, a “**Development and Regulatory Milestone**”) on a Program-by-Program basis. Takeda will notify Poseida of the achievement of each Development and Regulatory Milestone no later than [...\*\*\*...] after Takeda becoming aware of the achievement thereof. Thereafter, Poseida will provide Takeda with an invoice for the corresponding Development and Regulatory Milestone Payment, and Takeda will pay to Poseida such Development and Regulatory Milestone Payment no later than [...\*\*\*...] after receipt by Takeda thereof.

#	<u>Milestone Event</u>	<u>Milestone Payment</u>
1	[...***...]	[...***...]
2	[...***...]	[...***...]
3	[...***...]	[...***...]
4	[...***...]	[...***...]
5	[...***...]	[...***...]

Each Development and Regulatory Milestone Payment set forth above shall be payable only once for the first occurrence of the specified milestone event for each Program, regardless of the number of Licensed Products that achieve the applicable milestone event with respect to such Program, and in no event will the Development and Regulatory Milestone Payments set forth in this Section 6.4 exceed [...\*\*\*...] per Program. In the event that Development and Regulatory Milestone number [...\*\*\*...] is skipped, it will be payable at the next milestone event (that is, achievement of Development and Regulatory Milestone number [...\*\*\*...]). For clarity, if a Development and Regulatory Milestone Payment is made with respect to a milestone event for a Program and subsequently there is [...\*\*\*...], then the achievement of such milestone event with respect to such [...\*\*\*...] shall not trigger another Development and Regulatory Milestone Payment.

6.5 Commercial Milestone Payments. As partial consideration for the exclusive rights and covenants granted by Poseida to Takeda pursuant to this Agreement, Takeda shall make non-refundable, non-creditable milestone payments (each, a “**Commercial Milestone Payment**”) to Poseida upon achievement of the milestones set forth below (each, a “**Commercial Milestone**”) on a Program-by-Program basis. Takeda will notify Poseida of the achievement of each Commercial Milestone no later than [...\*\*\*...] after the end of the Calendar Year in which such Commercial Milestone is achieved. Thereafter, Poseida will provide Takeda with an invoice for the corresponding Commercial Milestone Payment, and Takeda will pay to Poseida such Commercial Milestone Payment no later than [...\*\*\*...] following receipt by Takeda thereof.

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<b>Commercial Milestone Event</b>	<b>Commercial Milestone Payment</b>
[...***...]	[...***...]
[...***...]	[...***...]
[...***...]	[...***...]
[...***...]	[...***...]
[...***...]	[...***...]

Each Commercial Milestone Payment set forth above shall be payable only once, upon the first occurrence of the applicable Commercial Milestone. For the avoidance of doubt, in no event shall the aggregate amount of the Commercial Milestone Payments set forth in this Section 6.5 exceed [...\*\*\*...] per Program. In the event that [...\*\*\*...] or more Commercial Milestones are achieved in the same Calendar Year, then all such Commercial Milestones will be paid in such Calendar Year.

6.6 Royalties.

(a) Subject to this Section 6.6, as partial consideration for the exclusive rights and covenants granted by Poseida to Takeda pursuant to this Agreement, during the Royalty Term, Takeda shall pay to Poseida a royalty on aggregate, worldwide annual Net Sales of each Licensed Product in the Territory during each Calendar Year at the following rates:

<b>Increments of Worldwide Aggregate Annual Net Sales in a Calendar Year</b>	<b>Royalty Rate</b>
Calendar Year Net Sales up to [...***...]	[...***...]
Calendar Year Net Sales from [...***...] up to and including [...***...]	[...***...]
Calendar Year Net Sales from [...***...] up to and including [...***...]	[...***...]
Calendar Year Net Sales that exceeds [...***...]	[...***...]

Royalties will be paid on a quarterly basis within the later of (i) [...\*\*\*...] after receipt by Takeda of an invoice from Poseida setting forth the royalty amount due as stated in the royalty

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report for each Calendar Quarter under Section 6.6(d) or (b) [...\*\*\*...] after the end of each Calendar Quarter.

(b) Royalty Term. Royalties will be payable on a Licensed Product-by-Licensed Product and country-by-country basis from the date of the First Commercial Sale of a Licensed Product until the later of (i) ten (10) years from First Commercial Sale of such Licensed Product in such country, (ii) expiry of the last Valid Claim of any Licensed Patent Rights [...\*\*\*...] or (iii) the expiration of regulatory exclusivity for such Licensed Product in such country (the "**Royalty Term**").

(c) Royalty Reductions. Notwithstanding the foregoing (and subject to Section 7.6(c)(ii)):

(i) in the event that a Licensed Product is sold in a country or other jurisdiction and [...\*\*\*...], the royalty rate set forth in Section 6.6(a) shall be reduced by [...\*\*\*...] with respect to such country or other jurisdiction;

(ii) in the event that [...\*\*\*...] (subject to Section 7.6(e));

(iii) in the event that [...\*\*\*...];

(iv) in the event that [...\*\*\*...]; and

(v) In no event will [...\*\*\*...]

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[...\*\*\*...].

(d) Royalty Reports. Takeda shall calculate all amounts payable to Poseida pursuant to this Section 6.6 at the end of each Calendar Quarter. Within [...\*\*\*...] of the end of each Calendar Quarter, Takeda shall provide to Poseida a statement of the amount of Net Sales of each Licensed Product in each country or other jurisdiction in the Territory during the applicable Calendar Quarter, in sufficient detail to permit confirmation of the accuracy of the royalty payment made, the gross sales and Net Sales of Licensed Products by country or jurisdiction, as applicable (including the deductions from gross sales to arrive at Net Sales and any withholding taxes required to be withheld hereunder, if any) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. If no royalties are due for any Calendar Quarter hereunder Takeda will so report. Any such information shared by Takeda under this Section 6.6(d) shall be deemed Takeda's Confidential Information.

6.7 Financial Records.

Each Party shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to Research Costs, including books and records of actual expenditures with respect to the budgets set forth in each Research Plan, in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by such Party and its Affiliates until the later of (a) [...\*\*\*...] after the end of the period to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (including any extensions thereof), or for such longer period as may be required by applicable Law.

6.8 Audits.

At the request of the other Party, each Party shall, and shall cause its Affiliates to, permit an independent public accounting firm of nationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to Section 6.7 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any [...\*\*\*...] more than [...\*\*\*...] after the end of such [...\*\*\*...], (b) be conducted more than [...\*\*\*...] in any [...\*\*\*...] period (unless a previous audit during such [...\*\*\*...] period revealed an underpayment with respect to such period) or (c) be repeated for any [...\*\*\*...]. The accounting firm shall disclose to the auditing Party only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than the greater of [...\*\*\*...] and [...\*\*\*...] from the reported amounts, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 6.9 below, if such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in either case ((i) or (ii)), within [...\*\*\*...] after the date on which such audit is completed by the auditing Party.

6.9 Audit Dispute.

In the event of a dispute with respect to any audit under Section 6.8, Poseida and Takeda shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [...\*\*\*...], the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "Audit Arbitrator"). If resolved by an Audit Arbitrator, the decision of the Audit Arbitrator shall

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be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Audit Arbitrator shall determine. Not later than [...\*\*\*...] after the decision by the Audit Arbitrator and in accordance with such decision, the audited Party shall pay the additional amounts, or the auditing Party shall reimburse the excess payments, as applicable.

6.10 Currency Exchange.

For purposes of determining the Commercial Milestone Payments and royalties payable hereunder, sales of Licensed Products invoiced in a currency other than Dollars shall be expressed in their Dollar equivalent calculated using Takeda's own standard currency translation methodology for the conversion of foreign sales currencies into Dollars, which methodology shall be in accordance with the Applicable Accounting Standards and shall be the methodology generally used by Takeda for currency conversions in Takeda's audited financial statements.

6.11 Manner of Payment.

Any payment to be made by one Party to the other Party under this Agreement shall be payable in Dollars and shall be paid by wire transfer in immediately available funds to the bank account designated by the payee Party. Each Party shall have the right to change such information at any time by providing written notice to the other Party; *provided* that such new bank information shall not be deemed effective until the date that is [...\*\*\*...] weeks after the receipt of such new information.

6.12 Tax.

(a) Withholding Tax. The amounts payable pursuant to this Agreement shall not be reduced on account of any Taxes unless required by applicable Law. Takeda shall deduct and withhold from its payments any Taxes that it is required by applicable Law to deduct or withhold. Prior to making any deduction or withholding in respect of Taxes from any payment under this Agreement, Takeda shall (i) timely provide a prior written notice to Poseida of the amounts subject to deduction or withholding, and the legal basis therefore (ii) inform Poseida in writing of any the forms, certificates or other items that are necessary in order to reduce or eliminate such deduction or withholding; and (iii) provide to Poseida a reasonable opportunity to furnish such forms, certificates or other items that would reduce or eliminate such deduction or withholding. In such case Takeda shall apply the reduced rate of withholding, or not withhold, as the case may be; *provided* that Takeda is in receipt of evidence, in a form reasonably satisfactory to Takeda, for example Poseida's delivery of all applicable documentation, at least [...\*\*\*...] weeks prior to the time that the payments are due. If, in accordance with the foregoing, there is no applicable Tax treaty, or the applicable Tax treaty reduces but does not eliminate the required withholding for Taxes, then, except as otherwise provided in Section 6.12(d), Takeda shall (1) withhold the amount required by Law from any payment due to Poseida under this Agreement and pay to Poseida the balance when due, (2) timely pay such amount to the proper taxing authority, and (3) promptly send to Poseida the best available evidence of such payment, including official receipts.

(b) Tax Cooperation. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Law, of withholding Taxes, VAT or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding Tax, VAT or similar obligations.

(c) Tax Exemptions, Credits and Deductions. The Parties will reasonably cooperate with each other in seeking any Tax exemption or credits that may be available with respect to any Licensed Product, including the Tax credit available under Section 45C of the Code by reason of a Party's Development expenditures contributing to the Licensed Product being granted orphan drug status by the FDA, or equivalent applicable Law of any other country and the

deduction available under Section 250 of the Code relating to foreign-derived intangible income, or any successor provision. Takeda shall use commercially reasonable efforts to provide, and to cause its Affiliates, subcontractors, sub-licenses, customers and applicable Third Parties to provide, any information and documentation reasonably requested by Poseida to obtain the benefits of Section 250 of the Internal Revenue Code of 1986, as amended (or any successor provision) and the applicable Treasury Regulations including, without limitation, information required to demonstrate the extent to which the Licensed Products will be sold, consumed, used and/or manufactured outside the United States.

(d) Redomicile, Assignment or Sublicense. Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that if either Party redomiciles, or assigns or sublicenses its rights or obligations under this Agreement (including an assignment of this Agreement as permitted under this Agreement), and such action leads to the imposition of withholding Tax liability or VAT on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then such Party will increase such payment by the amount necessary to ensure that the other Party receives an amount equal to the amount it would have received had no such action occurred.

(e) VAT/Sales Tax. All payments or amounts due under this Agreement, whether monetary or non-monetary are exclusive of VAT/sales tax and their equivalents. Takeda hereby covenants that it will pay any such VAT/sales tax correctly charged in addition to any amounts due under this Agreement. Where the prevailing legislation requires a VAT/sales tax reverse charge, then Takeda covenants that it shall correctly account for VAT/sales tax in respect of the services received. Poseida agrees that it will raise a tax invoice (or equivalent document) to support the charge to VAT/sales tax. If Poseida bears any VAT/ sales taxes directly related to amounts due under this Agreement from Takeda, Takeda shall reimburse Poseida for such taxes promptly upon receipt of an invoice. For the purposes of VAT, the services, rights and licenses provided by Poseida under this Agreement shall be considered to be Taxed under by Art 44 of Council Directive 2006/112/EC or any equivalent provision in the country of performance if performed outside the European Union and as such will be considered to be taxed for VAT/sales taxes purposes in the country of the recipient. Any supply of products or provision of services under this Agreement shall be Taxed (where applicable) in accordance with the prevailing VAT/sales tax legislation. The Parties agree that they will reasonably cooperate to ensure the use of any VAT/sales tax exemptions, suspensions or other reliefs.

## ARTICLE VII

### INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

#### 7.1 Disclosure.

During the Term, each Party shall promptly disclose and report to the other Party each discovery, improvement, Invention, idea, process and technique, whether or not patentable, made, conceived or first reduced to practice, whether solely by Poseida or its representatives, solely by Takeda or its representatives, or jointly by Poseida or its representatives and by Takeda or its representatives (or Affiliates or Sublicensees), alone or jointly with any Third Party, arising out of the performance of activities under the Collaboration ("**Arising IP**"). Such disclosure shall be made in reasonable scientific detail within [...\*\*\*...] of personnel responsible for Intellectual Property management of such Party first being advised of the Arising IP.

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(a) Ownership of Background IP.

(i) Poseida Background IP. As between the Parties, Poseida owns and Controls all right, title and interest in and to all Intellectual Property that is owned or Controlled by Poseida as of the Effective Date, including Licensed IP as of the Effective Date, or that is generated or acquired by Poseida outside of the scope of this Agreement ("**Poseida Background IP**").

(ii) Takeda Background IP. As between the Parties, Takeda owns and Controls all right, title and interest in and to all Intellectual Property that is owned or Controlled by Takeda as of the Effective Date or generated or acquired outside the scope of this Agreement ("**Takeda Background IP**").

(b) Ownership of Arising IP. All determinations of ownership of Arising IP shall follow inventorship in accordance with US patent law, except that regardless of inventorship, the following shall apply:

(i) [...\*\*\*...]

(ii) [...\*\*\*...]

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[...\*\*\*...].

(3)

[...\*\*\*...].

(iii) Joint Arising IP. Ownership of all Inventions and Intellectual Property rights therein arising out of the performance of the activities under the Collaboration that is neither Takeda Arising IP nor Poseida Arising IP shall be jointly owned by Takeda and Poseida (“**Joint Arising IP**”). Subject to the licenses granted under this Agreement, and the obligations of the Parties under Section 5.4, each Party shall have the right to Exploit the Joint Arising IP without a duty of seeking consent from or accounting to the other Party.

(iv) Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, licensees and sublicensees to so disclose, the conception, discovery, development, making, or reduction to practice of any Joint Arising IP and any Poseida Arising IP or Takeda Arising IP, as applicable, to be assigned by such Party to the other Party pursuant to this Section 7.2(b).

### 7.3 Prosecution and Maintenance of Patent Rights.

(a) Takeda has the sole right (but not the obligation) to control the filing, prosecution and maintenance of (including the defense of any interference or derivation proceeding, opposition or any other pre- or post-grant proceedings or challenges, including any patent term extensions) of all Takeda Patents and all Patent Rights within the Takeda Background IP, using counsel of its own choice.

(b) Poseida has the first right (but not the obligation) to control the filing, prosecution and maintenance of (including the defense of any interference or derivation proceeding, opposition or any other pre- or post-grant proceedings or challenges, including any patent term extensions) all Poseida Patents and all Patent Rights within the Poseida Background IP, using counsel of its own choice; *provided*, that with respect to Licensed Patent Rights that [...\*\*\*...]. In the event that Poseida decides not to prepare, file, prosecute, defend or maintain a Poseida Patent that Covers a Licensed Product or a component thereof in a country or other jurisdiction in the Territory, Poseida shall provide reasonable prior written notice to Takeda of such intention, and Takeda shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, defense and maintenance of such Poseida Patent at Takeda’s expense in such country or other jurisdiction. Upon Takeda’s written acceptance of such option, Takeda shall assume the responsibility and control for the preparation, filing, prosecution, and maintenance of such Poseida Patent. In such event, Poseida shall reasonably cooperate with Takeda in such country or other jurisdiction as provided under Section 7.4, *provided*, that, in the event this Agreement terminates in its entirety, Takeda shall no longer have the right to control or direct the preparation, filing, prosecution, defense and maintenance of any such Poseida Patent for which it has assumed control under this Section 7.3(b), and Poseida shall assume the responsibility and

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control for the preparation, filing, prosecution, and maintenance of such Poseida Patents, and Takeda shall cooperate in transitioning such control back to Poseida (or Poseida's designee).

(c) Takeda shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain the Joint Patents worldwide, at Takeda's sole cost and expense and in the name of both Parties. Takeda shall keep Poseida fully informed of all material steps with regard to the preparation, filing, prosecution, and maintenance of Joint Patents, including by providing Poseida with a copy of material communications to and from any patent authority in the Territory regarding such Joint Patents, and by providing Poseida drafts of any material filings or responses to be made to such patent authorities in the Territory sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Poseida to review and comment thereon. Takeda shall consider in good faith the requests and suggestions of Poseida with respect to such Takeda drafts and with respect to strategies for filing and prosecuting the Joint Patents in the Territory. In the event that Takeda decides not to prepare, file, prosecute, or maintain a Joint Patent in a country or other jurisdiction in the Territory, Takeda shall provide reasonable prior written notice to Poseida of such intention (which notice shall, in any event, be given no later than [...\*\*\*...] prior to the next deadline for any action that may be taken with respect to such Joint Patent in such country or other jurisdiction), and Poseida shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Joint Patent at its expense in such country or other jurisdiction. Upon Poseida's written acceptance of such option, Poseida shall assume the responsibility and control for the preparation, filing, prosecution, and maintenance of such specific Joint Patent at its sole cost and expense. In such event, Takeda shall reasonably cooperate with Poseida in such country or other jurisdiction as provided under Section 7.4 and Poseida's interest in such Joint Patent shall no longer be included in the Licensed IP.

7.4 Cooperation.

Each Party hereby agrees: (a) to cooperate, and to cause any of its Affiliates and their respective employees, agents and consultants to cooperate, with the other Party to effectuate and perfect the ownership contemplated by this Agreement, including by promptly executing and recording assignments and other documents consistent with the ownership set forth in this Agreement; (b) to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake patent prosecution; (c) to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to Patent Rights licensed under this Agreement; (d) to discuss and coordinate with the other Party through the Patent Subcommittee with respect to strategies for filing the Arising Product Patents, including with respect to the separation of Licensed Product-related and any Poseida Technology Platform-related subject matter; (e) work in good faith with the other Party and the Patent Subcommittee to determine Poseida Arising IP and Takeda Arising IP pursuant to Section 7.2(b)(i) and Section 7.2(b)(ii), respectively, and Joint Arising IP pursuant to Section 7.2(b)(iii), which determination shall be made only upon the mutual agreement of the Parties, subject to Section 12.3; (f) to endeavor in good faith to coordinate its efforts with the other Party through the Patent Subcommittee to minimize or avoid interference with the prosecution and maintenance of the other Party's patent applications; and (g) with respect to Takeda, to keep Poseida reasonably informed regarding the status and material activities with regard to the prosecution and maintenance of any Patent Right that claims any Arising Product IP, except with respect to a Takeda Payload or component thereof ("**Arising Product Patent**"), including by providing Poseida with a copy of material communications to and from any patent authority in the Territory regarding such Arising Product Patents.

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7.5 Patent Expenses.

The patent filing, prosecution and maintenance expenses incurred after the Effective Date with respect to Patent Rights shall be borne by the Party having the right to file, prosecute and maintain such Patent Rights under Section 7.3.

7.6 Third Party Infringement and Validity Challenges.

(a) Notices. Each Party shall promptly report in writing to the other Party any (i) known or suspected infringement by a Third Party of any Licensed Patent Rights, or (ii) unauthorized use or misappropriation of any Confidential Information or Know-How of a Party by a Third Party of which it becomes aware (each, a "**Third Party Infringement**"), and shall provide the other Party with all available evidence of such Third Party Infringement.

(b) Patent Validity Challenges. Each Party shall notify the other Party if it receives a notice of any legal or administrative action by a Third Party against a Licensed Patent Right, including any oppositions, nullity actions, revocations, inter partes reviews, post grant reviews, compulsory license proceedings or declaratory judgment actions. Poseida shall have the first right, but not the obligation, to defend any validity challenges against the Licensed Patent Rights, including against all declaratory judgment actions, any compulsory licensing proceedings and any post-grant proceedings before the United States Patent Office or a foreign patent office. Poseida shall keep Takeda reasonably informed as to the status of such actions and proceedings and shall consider in good faith any reasonable comments from Takeda with respect thereto. If Poseida elects not to defend such validity challenges with respect to a Licensed Patent Right that Covers a Licensed Product or a component thereof, Poseida shall inform Takeda in writing and Takeda may elect to defend such validity challenge at Takeda's sole cost and expense, and Takeda shall keep Poseida reasonably informed as to the status of such actions and proceedings and shall consider in good faith any reasonable comments from Poseida with respect thereto; *provided*, that, in the event this Agreement terminates in its entirety, Takeda shall no longer have the right to control the defense to such challenge, and Poseida may assume control of such defense, and Takeda shall cooperate in transitioning such control back to Poseida (or Poseida's designee).

(c) Rights to Enforce.

(i) Takeda Background IP; Takeda Arising IP. As between the Parties, Takeda shall have the sole and exclusive right, but not the obligation, to initiate and manage any Action anywhere in the world relating to any Third Party Infringement of the Takeda Background IP and Takeda Arising IP at its sole expense.

(ii) Licensed IP. As between the Parties, Poseida shall have the sole and exclusive right, but not the obligation, to initiate and manage any Action anywhere in the world relating to any Third Party Infringement of the Poseida Background IP and Poseida Arising IP. Poseida shall keep Takeda reasonably informed with regard to the preparation and filing of such infringement action and shall consider in good faith the requests of Takeda with respect to strategies for the infringement action. [...\*\*\*...].

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(iii) Joint Arising IP. Takeda shall have the first right, but not the obligation, to initiate and manage of any Action in the Field and in the Territory relating to any Third Party Infringement of the Joint Arising IP. Poseida shall have a right to comment on Takeda's enforcement strategy, and Takeda shall reasonably consider any such comment. Poseida shall join any such Action, at Takeda's request and expense. If Takeda does not wish to exercise the foregoing right, it shall provide Poseida with written notice that Takeda declines such right, and Poseida shall have the right, but not the obligation, to initiate or manage such Action at its own expense.

(d) Procedures; Expenses and Recoveries. The Party having the right to initiate or manage any Third Party Infringement Action under Section 7.6(b) shall have the sole and exclusive right to select counsel for any such Action and shall pay all expenses of such Action, including attorneys' fees and court costs and reimbursement of the other Party's reasonable out-of-pocket expense in rendering assistance requested by the first Party. If (i) required under Law in order for the initiating Party to initiate or maintain such Action, (ii) either Party is unable to initiate or prosecute such Action solely in its own name or (iii) it is otherwise advisable to obtain an effective legal remedy, then in each such case, the other Party shall join as a party to such Action and will execute and cause its Affiliates to execute all documents, and take all actions, reasonably necessary for the initiating Party to initiate and maintain such Action. In addition, at the initiating Party's request, the other Party shall provide other reasonable assistance to the initiating Party in connection with such Action at no charge to the initiating Party except for reimbursement by the initiating Party of reasonable out-of-pocket expenses incurred in rendering such assistance. The non-initiating Party shall have the right to participate and be represented in any such Action under Section 7.6(b) by its own counsel at its own expense. If the Parties obtain from a Third Party, in connection with any such Action under Section 7.6(b), any damages, license fees, royalties or other compensation (including any amount received in settlement of such suit), such amounts shall be allocated in all cases as follows:

(i) [...\*\*\*...]

(ii) [...\*\*\*...].

(e) Party Infringement of Third Party IP. If either Party becomes aware that the Exploitation of any Licensed Product in the Territory results in, or may result in, any Action, by a Third Party alleging infringement of Patent Rights or unauthorized use or misappropriation of Confidential Information or Know-How by a Party or its Affiliates or Sublicensees (a "**Collaboration Infringement**"), then such Party shall promptly report such Collaboration Infringement in writing to the other Party. [...\*\*\*...]. Furthermore, Takeda shall have the first right, but not the obligation, to defend and control the defense of any such Action at its own expense, using counsel of its own choice; *provided*, that Poseida shall pay all expenses in connection with the defense of any Action or portion thereof to

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the extent related to the Poseida Technology Platform. Poseida may participate in any such Action with counsel of its choice at its own expense. Without limitation of the foregoing, if Takeda finds it necessary or desirable to join Poseida as a party to any such action, Poseida shall, at Takeda's cost and expense, execute all papers and perform such acts as shall be reasonably required. If Takeda elects (in a written communication to be submitted to Poseida within a reasonable amount of time after notice of the alleged Collaboration Infringement) not to defend or control the defense of such Action, Poseida may conduct and control the defense of any such Action, at its own expense; *provided*, that, if Poseida obtains a license from a Third Party with respect to a Collaboration Infringement to the extent necessary to Exploit Licensed Products pursuant to this Agreement, then Takeda shall have rights to such license as provided in this Agreement. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such Action. If the Parties obtain from a Third Party, in connection with any such Action under this Section 7.6(e), any damages, license fees, royalties or other compensation (including any amount received in settlement of such suit), such amounts shall be allocated in all cases as follows:

- (i) [...\*\*\*...]
- (ii) [...\*\*\*...].

7.7 Common Interest.

The Parties acknowledge and agree that, with respect to the prosecution, maintenance, enforcement and defense of Licensed Patent Rights, [...\*\*\*...]. The Parties agree and acknowledge that [...\*\*\*...].

7.8 Trademarks.

Takeda and its Related Parties have the sole right to use any trademark that Takeda Controls for Licensed Products in the Territory at its sole discretion. Takeda will develop one or more Product Trademark(s) for use by Takeda and its Related Parties in the Territory to Commercialize Licensed Products which have received Regulatory Approval in the Field in the Territory. Takeda (or its Related Parties, as appropriate) shall own all rights to such Product Trademarks and all goodwill associated therewith throughout the Territory and the rights to any internet domain names incorporating the applicable Product Trademarks or any variation or part of such Product Trademarks used as its URL address or any part of such address. Upon mutual agreement of the Parties, Takeda may use the Poseida Platform Trademarks in connection with its Exploitation of the Licensed Products, subject to customary terms related to marking, quality control, approval and inspection mutually agreed by the Parties prior to the first use thereof. Each Party and its Related Parties shall retain all right, title and interest in and to its and their respective corporate names and logos. For the avoidance of doubt, neither Party shall have any right to use the other Party's or the other Party's Related Parties' corporate names or logos in connection with Commercialization of Licensed Products without the prior written consent of the other Party.

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ARTICLE VIII

**CONFIDENTIAL INFORMATION**

8.1 **Nondisclosure Obligation.**

(a) At all times during the Term and for a period of [...\*\*\*...] following termination or expiration of this Agreement in its entirety, all Confidential Information disclosed by one Party (the "**Disclosing Party**") to, or otherwise accessed by, the other Party (the "**Receiving Party**") hereunder shall be maintained in confidence by the Receiving Party and shall not be published or otherwise disclosed to a Third Party or used for any purpose except as expressly set forth herein without the prior written consent of the Disclosing Party; *provided* that the confidentiality obligations with respect to any Confidential Information that the Disclosing Party identifies as a trade secret shall extend until such Confidential Information is no longer a trade secret under applicable Law. Information exchanged by the Parties pursuant to the Confidentiality Agreement shall be deemed Confidential Information disclosed under this Agreement, and shall be subject to the terms of this Agreement from and after the Effective Date. Each Party may use the other Party's Confidential Information solely to the extent required to perform its obligations or exercise any rights under this Agreement. The confidentiality and non-use provisions of this **ARTICLE VIII** shall not apply to the extent that the Receiving Party can demonstrate by competent evidence that such Confidential Information:

(i) is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party's business records;

(ii) is in the public domain or publicly known by use or publication before its receipt from the Disclosing Party, or thereafter enters the public domain or becomes publicly known through no fault of the Receiving Party;

(iii) is subsequently disclosed to the Receiving Party by a Third Party without restriction who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(iv) is developed by the Receiving Party independently of Confidential Information received from the Disclosing Party and independent of the Collaboration, as documented by the Receiving Party's business records.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

(b) Notwithstanding the obligations of confidentiality and non-use set forth in **Section 8.1(a)** and **Section 8.2**, the Receiving Party may disclose Confidential Information of the Disclosing Party, and disclose the existence and terms of this Agreement, to the extent such disclosure is reasonably required, to (i) Related Parties, and its and their employees, directors, agents, consultants, advisors, and Third Party contractors who have a need to know such

\*\*\* Certain Confidential Information Omitted

Confidential Information for the performance of its obligations (or for such entities to determine their interest in performing such activities) in accordance with this Agreement, or, in the case of Takeda, as necessary to Exploit the Licensed Products or determine its interest in exercising a License Option, in each case who are obligated to keep such Confidential Information confidential and use such Confidential Information on terms no less stringent than those in this Section 8.1; (ii) Governmental Authorities or other Regulatory Authorities in order to obtain and maintain Patent Rights and Regulatory Approvals in accordance with this Agreement, or otherwise perform its obligations or exploit its rights under this Agreement, *provided*, that such Confidential Information shall be disclosed only to the extent reasonably necessary to do so; (iii) prosecute or defend litigation, including by responding to a subpoena in a Third Party litigation; (iv) the extent required by a court, administrative order or Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity; and (v) any bona fide actual or prospective underwriters, investors, lenders, other financing sources, acquirers, permitted Sublicensees, collaborators or strategic partners and to consultants and advisors of such Party, in each case who are obligated to keep such Confidential Information confidential and use such Confidential Information on terms no less stringent than those in this Section 8.1.

(c) If a Receiving Party is required by Law (including regulations promulgated by securities exchanges or listing entities) to disclose Confidential Information of the Disclosing Party pursuant to Sections 8.1(b)(ii), 8.1(b)(iii) or 8.1(b)(iv), such Party shall, to the extent permitted by Law, promptly inform the Disclosing Party of the disclosure that is being sought (and to the extent possible, at least [...\*\*\*...] notice) in order to provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations and the Receiving Party shall endeavor in good faith, at the Disclosing Party's expense, to secure confidential treatment of such Confidential Information or reasonably assist the Disclosing Party in seeking a protective order or other confidential treatment. Confidential Information that is required to be disclosed by Law shall remain otherwise subject to the confidentiality and non-use provisions of this Section 8.1 and Section 8.2. If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, at least [...\*\*\*...] in advance of any such filing, such Party will provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with a reasonable opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable and timely comments into consideration before so filing this Agreement.

## 8.2 Publication and Publicity.

(a) Publication. Each Party recognizes that the publication of papers regarding results of and other information regarding activities pursuant to the Collaboration, including oral presentations and abstracts, may be beneficial to both Parties; *provided* that such publications are subject to reasonable controls to protect the Confidential Information of the Parties. In particular, it is the intent of the Parties to maintain the confidentiality of any Confidential Information included in any Invention disclosures or any draft patent application until such patent application has been filed. Subject to the foregoing, [...\*\*\*...]

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[...\*\*\*...].

(b) Publicity.

(i) The Parties have agreed upon the content of a press release which shall be issued by Poseida and substantially in the form attached hereto as Exhibit 8.2(b). The Parties shall reasonably coordinate in order to issue such press release promptly upon execution of this Agreement. Except as set forth in Section 8.1, Section 8.2(a) and Section 8.2(b)(ii) or as otherwise expressly permitted by this Agreement, the terms of this Agreement may not be disclosed by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Law.

(ii) Notwithstanding the foregoing, Takeda and its Related Parties may make public announcements or disclosures necessary or useful to Develop or Commercialize the Licensed Products, including disclosures regarding clinical studies and disclosures to advertise, promote and otherwise Commercialize the Licensed Products.

8.3 Return of Confidential Information.

Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which such other Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; *provided, however*, the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such other Party's archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose. The confidentiality and non-use provisions set forth in this ARTICLE VIII shall survive expiration or termination of this Agreement.

\*\*\* Certain Confidential Information Omitted

## ARTICLE IX

### REPRESENTATIONS, WARRANTIES AND COVENANTS

#### 9.1 Mutual Representations and Warranties.

Each Party represents and warrants to the other Party that, as of the Effective Date:

(a) Representations of Authority. It is duly organized and validly existing under the Laws of its jurisdiction of incorporation or formation, and has full corporate right, power and authority to enter into this Agreement and to perform its obligations under this Agreement.

(b) Consents. All necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained.

(c) No Conflict. The execution and delivery of this Agreement and the performance of its obligations hereunder (i) do not violate or conflict with the provisions of its certificate of incorporation or by-laws, (ii) do not conflict with or violate any requirement of Law effective as of the Effective Date, and (iii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of it or any of its Affiliates existing or known as of the Effective Date.

(d) Authorization and Binding Nature. The execution, delivery and performance of this Agreement and the performance of all obligations hereunder have been duly authorized by all requisite corporate action on the part of such Party. This Agreement constitutes the valid and legally binding obligations of such Party, except as may be limited by applicable bankruptcy, insolvency, reorganization, moratorium and other Laws of general application affecting the enforcement of creditors' rights generally and Laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(e) No Debarment. Neither it nor any of its Affiliates, nor its or their respective employees, have been Debarred or are subject to Debarment.

(f) No Misstatements or Omissions. The representations and warranties of such Party in this Agreement, and the information, documents and materials furnished to the other Party in response to such Party's written requests for due diligence information prior to the Effective Date, do not, taken as a whole, (i) contain any untrue statement of a material fact, or (ii) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading.

(g) Protection of Information. Each Party agrees that during the Term of this Agreement, and without limiting its obligations hereunder, each Party shall implement technical and organizational measures to protect all Confidential Information under this Agreement that are appropriate and that provide no less protection than such Party's measures to protect its own information of a similar nature or importance.

#### 9.2 Representations and Warranties of Poseida.

Poseida represents and warrants to Takeda that, as of the Effective Date:

(a) Ownership. (i) Poseida is the sole and exclusive owner of, or otherwise has the right to license, the Licensed IP, (ii) Poseida has the right to grant to Takeda the licenses hereunder, and (iii) there are no contractual or other obligations entered into by Poseida which

would limit or otherwise prevent Poseida from granting the rights purported to be granted to Takeda in this Agreement.

(b) Notice of Infringement. Neither Poseida nor any of its Affiliates have received any written notice of any claim that any Intellectual Property right Controlled by a Third Party would be infringed or misappropriated by the exploitation of the Licensed IP or Excluded In-License Agreements as contemplated by the Research Plans.

(c) No Infringement. To Poseida's Knowledge, the conception, development and reduction to practice of the Licensed IP have not constituted or involved the infringement or misappropriation of Patent Rights, Know-How or similar rights or property of any Person.

(d) No Claim. There is no (i) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal Action of any nature, civil, criminal, regulatory or otherwise, pending or, to Poseida's Knowledge, threatened against Poseida or any of its Related Parties or (ii) judgment or settlement against or owed by Poseida or any of its Related Parties, in each case in connection with the Licensed IP.

(e) Employee Obligations. All of Poseida's employees, officers and consultants performing activities under this Agreement on behalf of Poseida have executed agreements or have existing obligations under Law requiring assignment to Poseida or its Affiliates of all Intellectual Property and proprietary rights made during the course of and as the result of their association with Poseida, including all Intellectual Property created in the performance of this Agreement, or otherwise granting to Poseida or its Affiliates sufficient rights to such inventions to the extent necessary to effect the license and ownership provisions of this Agreement, in each case obligating such individuals to maintain as confidential the Confidential Information of Poseida and the Confidential Information of Takeda as the Disclosing Party under this Agreement.

(f) Material Information. As of the Effective Date, (i) Poseida has provided or made available to Takeda true, correct and complete copies of all In-License Agreements and Excluded In-License Agreements and (ii) to Poseida's Knowledge, all other information with respect to the Licensed Know-How and Licensed Patent Rights provided or made available to Takeda is true, correct and complete.

(g) Third Party Agreements. Neither Poseida nor any of its Affiliates has previously entered into, nor will enter into during the Term, any agreement, whether written or oral, with respect to the Licensed IP (including by granting any covenant not to sue with respect thereto) that would conflict with or otherwise diminish the rights granted to Takeda hereunder.

9.3 No Warranties.

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY TECHNOLOGY, PRODUCT, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING, AND EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE LICENSED PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO THE LICENSED PRODUCTS WILL BE ACHIEVED.

9.4 Additional Covenants.

(a) Conflicting Transactions. During the Term, neither Party will, or will allow its Affiliates to, enter into any agreement granting a license or other right that is inconsistent with the rights granted to the other Party under this Agreement.

(b) Compliance. Each Party and its Related Parties shall conduct the Collaboration and perform its obligations and other activities under this Agreement in accordance in all material respects with all Laws and industry standards, including, to the extent applicable, then-current governmental regulations concerning good laboratory practices, good clinical practices and good manufacturing practices. Neither Party shall export any technology licensed to it by the other Party under this Agreement, except in compliance with applicable export Laws.

(c) Debarment. Neither Party nor any of its Affiliates will use in any capacity, in connection with the Collaboration or the performance of its obligations under this Agreement, any Person that has been Debarred. Each Party agrees to inform the other Party in writing promptly if it learns that it or any Person that is performing activities in the Collaboration or under this Agreement is Debarred or is subject to Debarment, or, to the notifying Party's Knowledge, if Debarment of the notifying Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the Collaboration or the performance of its other obligations under this Agreement, is threatened.

(d) Existing Poseida In-License Agreements. Poseida shall (i) not amend, terminate or otherwise modify, or permit to be amended, terminated or modified, any of the In-License Agreements or Excluded In-License Agreements or (ii) exercise any right under any of the In-License Agreements or Excluded In-License Agreements, in each case of (i) and (ii), in a manner that impairs or diminishes the rights granted by Poseida to Takeda under such In-License Agreements or Excluded In-License Agreements. Poseida will promptly notify Takeda of any written notice that Poseida receives from the counterparty to any In-License Agreement or Excluded In-License Agreement alleging Poseida's material breach of such In-License Agreement or Excluded In-License Agreement. Without limiting any other right or remedy of Takeda under this Agreement and in order to prevent, ameliorate, mitigate or cure a material breach by Poseida of any In-License Agreement or Excluded In-License Agreement, in the event that Poseida receives notice from the counterparty to any In-License Agreement or Excluded In-License Agreement alleging the material breach by Poseida of such In-License Agreement or Excluded In-License Agreement, after promptly notifying Takeda in writing, if such material breach is not cured within [...\*\*\*...] after such written notice to Takeda, then Takeda shall have the right to perform such obligation on behalf of Poseida or otherwise remedy such material breach and Poseida shall reimburse Takeda for its costs and expenses in connection therewith.

(e) Exclusive License in [...\*\*\*...]. Poseida covenants that it will fulfill, by [...\*\*\*...], its [...\*\*\*...].

**ARTICLE X**

**TERM AND TERMINATION**

10.1 Term.

This Agreement shall be effective as of the Effective Date and, unless terminated earlier pursuant to Section 10.2 or Section 10.3, shall continue in force and effect until

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expiration of the last-to-expire Royalty Term for any and all Licensed Products (the "**Term**"). On a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of the Royalty Term for a Licensed Product in a country, the licenses granted to Takeda pursuant to Section 5.2(b) with respect to such Licensed Product in such country shall become fully paid-up, royalty-free, perpetual and irrevocable.

10.2 Termination for Convenience.

Takeda shall have the right to terminate this Agreement for any reason in its entirety or on a Program-by-Program or Licensed Product-by-Licensed Product basis, as applicable, on sixty (60) days' prior written notice to Poseida at any time.

10.3 Termination for Cause.

(a) This Agreement may be terminated at any time during the Term upon written notice by either Party (the "**Non-Breaching Party**") if the other Party (the "**Breaching Party**") is in material breach of its obligations hereunder and has not cured such breach within thirty (30) days in the case of a payment breach, or within sixty (60) days in the case of all other breaches, after notice requesting cure of the breach, or, if cure of such breach other than non-payment cannot reasonably be effected within such sixty (60)-day period, to deliver to the Non-Breaching Party a plan reasonably calculated to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing, but in no event more than an additional six (6) months. Following delivery of such a plan, the Breaching Party will carry out the plan and cure the breach. If the Breaching Party fails to cure a material breach of this Agreement as provided above, then the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party.

(b) If the alleged Breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 10.3(a) or disputes that it has not timely cured such breach, and such alleged Breaching Party provides the other Party notice of such dispute within such thirty (30) or sixty (60)-day period, as applicable, then the Non-Breaching Party shall not have the right to terminate this Agreement under Section 10.3(a) unless and until such dispute is resolved in accordance with ARTICLE XII. It is understood and agreed that, during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(c) Termination for Safety Concern. On a Licensed Product-by-Licensed Product basis, Takeda may, at its election, terminate this Agreement with respect to such Licensed Product immediately upon written notice to Poseida as a result of a Safety Concern.

(d) Termination for Insolvency. Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [... \*\*\* ...] of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

(e) Termination for Patent Challenge. Either Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if (i) a Party or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or

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enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Patent Right within (A) in the case where such Party is Takeda, the Licensed IP, and (B) in the case where such Party is Poseida, the Takeda Background IP or Takeda Arising IP (each, as applicable, a “**Patent Challenge**”) and (ii) such Party does not (A) [...] or (B) [...], in each case of (A) and (B), within [...]. Notwithstanding the foregoing, either Party may not terminate this Agreement due to a Patent Challenge if: (x) [...]; or (y) [...].

10.4 [...] Remedy. [...].

10.5 Effects of Termination.

(a) All Terminations. Upon any termination of this Agreement in whole or in part by either Party, the following terms will apply (in the event of a termination of this Agreement in part, the following shall apply with respect to the applicable Program or Licensed Product):

(i) The licenses granted by Poseida to Takeda pursuant to Section 5.2 shall terminate, and the license granted by Takeda to Poseida pursuant to Section 5.3 shall terminate.

(ii) Except as set forth in this Section 10.5, all of the rights and obligations of the Parties hereunder with respect to this Agreement shall terminate.

(iii) Poseida shall submit a final invoice for all Research Costs incurred up to the effective date of termination and [...] comprising such Research Costs (which, in the event of a termination by Takeda pursuant to Section 10.2, shall include any such [...] for the [...] period following such termination). Takeda shall pay all such amounts within [...] of receipt of such invoice.

(iv) Except in the event of a termination by Takeda pursuant to Section 10.3(c), Takeda may sell off its existing inventory of Licensed Products for a period of [...].

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(b) Takeda Termination for Convenience; Termination by Poseida for Breach or Insolvency. Upon any termination of this Agreement (in whole or in part) by Takeda pursuant to Section 10.2, or by Poseida pursuant to Section 10.3(a) or Section 10.3(d), at Poseida's sole election by written notice to Takeda (which Poseida shall have the right to exercise with respect to all or part of the following), the following shall apply:

(i) Poseida Reversion Rights.

(1) To the extent a Licensed Product under a terminated Program is comprised of [...\*\*\*...], Takeda shall grant, and hereby grants effective as of the effective date of such termination, to Poseida (A) a non-exclusive, royalty-bearing, worldwide, sublicensable, transferrable license under (I) [...\*\*\*...] and (II) [...\*\*\*...] (collectively, the "**Reversion IP**") to use, develop, manufacture, commercialize and otherwise fully exploit any Selected Candidate, Licensed Product or other product arising under any terminated Programs ("**Reversion Products**") in the Field in the Territory and (B) a right of reference to any Regulatory Approvals, regulatory documentation and data related to any Reversion Products. In consideration of the foregoing license under the Reversion IP, Poseida shall pay to Takeda [...\*\*\*...].

(2) Takeda shall reasonably cooperate with Poseida (or its designee(s)), at Poseida's cost, to facilitate a smooth, orderly and prompt transition of the activities related to the Reversion Products to Poseida or such designee, including making introductions to any Third Party providers, contract research organizations, CMOs or subcontractors engaged by Takeda prior to the applicable termination, including with respect to the control and completion of any ongoing clinical trials and the transition of any manufacturing activities to Poseida or its designee.

(3) Takeda shall assign, and hereby does assign effective upon such termination, to Poseida (A) [...\*\*\*...], and (B) [...\*\*\*...]. Notwithstanding anything herein to the contrary, all such [...\*\*\*...] shall be deemed the Confidential Information of Poseida. Takeda shall, as soon as practicable, transfer the foregoing [...\*\*\*...] reasonable assistance in the use and understanding thereof at [...\*\*\*...] cost and expense.

(4) Notwithstanding anything to the contrary herein, if a Licensed Product is terminated under this Agreement but [...\*\*\*...], there shall be no Reversion IP or Reversion Product.

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(ii) With respect to Licensed Products that are not Reversion Products, upon Poseida's request within [...\*\*\*...] following the effective date of termination, the Parties shall discuss [...\*\*\*...]. For clarity, [...\*\*\*...].

(iii) Takeda shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, [...\*\*\*...] this Section 10.5(b).

(c) Other Effects of Expiration or Termination. Except as otherwise set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation; *provided, however*, that Takeda shall have no obligation to make any milestone payment pursuant to ARTICLE VI with respect to any milestone achieved after the date on which a Party provides notice of termination pursuant to this Agreement but prior to the effective date of such termination. The following provisions shall survive any expiration or termination of this Agreement: ARTICLE I, Section 3.4(a) (solely with respect to any Research Costs incurred prior to termination), Section 3.5, Section 5.2(g) (solely with respect to any surviving recordkeeping and reporting obligations [...\*\*\*...]), Section 5.6, ARTICLE VI (solely with respect to amounts accrued or owing as of the effective date of termination and, in connection with any milestone payment pursuant to ARTICLE VI, subject to this Section 10.5(c)), Section 7.2, Section 7.5 (solely with respect to expenses incurred prior to termination), Section 7.7, Section 8.1, Section 8.2 (solely with respect to any paper proposed for publication by Poseida or any of its Related Parties [...\*\*\*...] or [...\*\*\*...]), Section 8.3, Section 9.3, Section 10.1 (last sentence only and only upon expiration), this Section 10.5, ARTICLE XI (solely with respect to claims for indemnification, if any, made prior to the effective date of termination) and ARTICLE XII. Except as set forth in this Section 10.5(c), upon termination or expiration of this Agreement all other rights and obligations of the Parties under this Agreement cease.

(d) Remedies. Each Party shall be free to seek, in accordance with Section 12.1 and Section 12.2, without restriction as to the number of times it may seek, damages, expenses and remedies that may be available to it under applicable Law or in equity and shall be entitled, at such Party's option and its sole discretion, to offset the amount of any damages and expenses obtained against the other Party in a final determination obtained in accordance with Section 12.1 and Section 12.2 against any amounts otherwise due to such other Party under this Agreement.

10.6 [...\*\*\*...]

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## ARTICLE XI

### INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

#### 11.1 Indemnification by Poseida.

Poseida shall indemnify, defend and hold harmless Takeda and its Affiliates and its and their directors, officers, employees, and agents (each, a “**Takeda Indemnitee**”) from and against any and all Losses of any Takeda Indemnitee as a result of any Third Party Claim to the extent such Losses arise out of: (a) the performance of the Research Activities by Poseida or its Related Parties, (b) the gross negligence or willful misconduct of any Poseida Indemnitee, (c) the breach by Poseida of any warranty, representation or covenant of Poseida in this Agreement, or (d) any Exploitation of the Licensed Products or Reversion Products by Poseida after the termination of this Agreement in part or in its entirety, if a license is granted to Poseida; except, in each case, to the extent such Losses arise out of any activities for which Takeda is obligated to indemnify any Poseida Indemnitee under Section 11.2.

#### 11.2 Indemnification by Takeda.

Takeda shall indemnify, defend and hold harmless Poseida and its Affiliates and its and their directors, officers, employees, and agents (each, a “**Poseida Indemnitee**”) from and against any and all Losses of any Poseida Indemnitee as a result of any Third Party Claim to the extent such Losses arise out of: (a) the performance of the Research Activities by Takeda or its Related Parties, (b) the Exploitation of the Licensed Products by Takeda or its Related Parties, (c) the gross negligence or willful misconduct of any Takeda Indemnitee, or (d) the breach by Takeda of any warranty, representation or covenant of Takeda in this Agreement; except, in each case, to the extent such Losses arise out of any activities for which Poseida is obligated to indemnify any Takeda Indemnitee under Section 11.1.

#### 11.3 Certain Losses.

Any Losses, other than those Losses covered in ARTICLE VII, or which result from the breach of a Party’s obligation under this Agreement or the unlawful conduct of a Party, or for which indemnification is otherwise provided in Section 11.1 or Section 11.2, in connection with any Third Party Claim brought against either Party resulting directly or indirectly from the performance of Research Activities (including from the Manufacture of any Licensed Product for use in such Research Activities) in accordance with the Research Plans shall be included as a Research Cost. If either Party learns of any Third Party Claim with respect to Losses covered by this Section 11.3, such Party shall provide the other Party with prompt written notice thereof. The Parties shall confer with respect to how to respond to such Third Party Claim and how to handle such Third Party Claim in an efficient manner. In the absence of such an agreement, each Party shall have the right to take such action as it deems appropriate.

#### 11.4 Procedure.

The Party claiming indemnity under Section 11.1 or Section 11.2 (the “**Indemnified Party**”) shall give written notice to the other Party (the “**Indemnifying Party**”) promptly after learning of the applicable Third Party Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party’s expense, in connection with the defense of such Third Party Claim. The Indemnified Party may participate in and monitor such defense with counsel of its own choice at its own expense; *provided, however*, that the Indemnifying Party shall have the right to assume and conduct the defense of such Third

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Party Claim with counsel of its choice. The Indemnifying Party shall not settle such Third Party Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, conditioned, or delayed, unless the settlement involves only the payment of money and no admission of wrong-doing or fault by the Indemnified Party. So long as the Indemnifying Party is actively defending the Third Party Claim in good faith, the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of such Third Party Claim, (a) the Indemnified Party may defend against and consent to the entry of any judgment, or enter into any settlement with respect to, such Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate, and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this ARTICLE XI.

11.5 General Limitation of Liability.

NEITHER PARTY WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS OR BUSINESS INTERRUPTION ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF (A) A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (B) A MATERIAL BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE VIII, OR (C) AMOUNTS PAID TO THIRD PARTIES IN CONNECTION WITH CLAIMS SUBJECT TO INDEMNIFICATION UNDER SECTION 11.1 or SECTION 11.2.

11.6 Insurance.

Each Party shall maintain insurance during the Term and for a period of at least [...\*\*\*...] after the last commercial sale of any Licensed Product under this Agreement by such Party or its Related Parties, with a reputable, solvent insurer in an amount [...\*\*\*...]. Upon reasonable request, each Party shall provide the other Party with evidence of the existence and maintenance of such insurance coverage. Notwithstanding the foregoing, Takeda will be permitted to satisfy any and all of its obligations under this Section 11.6 through a program of self-insurance, in whole or in part. The Parties acknowledge that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations under this Agreement.

**ARTICLE XII**

**MISCELLANEOUS**

12.1 Governing Law.

This Agreement shall be construed and the respective rights of the Parties determined according to the Laws of the State of New York, excluding any of its conflicts of laws principles to the contrary.

12.2 Jurisdiction.

The Parties hereby (a) irrevocably submit to the jurisdiction of the state and federal courts in the State of New York and agree that all claims shall be heard and determined in any such court, (b) waive any defense of inconvenient forum to the maintenance of any such claims and further agree not to bring any such claims in any other court, and (c) irrevocably consent to service of process by certified mailing, postage prepaid, or delivering such service to the Party at its respective notice address set forth in Section 12.6. Notwithstanding anything to the contrary in this Section 12.2, either Party may seek injunctive relief in any court in any jurisdiction where appropriate.

\*\*\* Certain Confidential Information Omitted

12.3 Patent and Trademark Disputes.

Notwithstanding any provision to the contrary set forth in this Agreement, any and all issues regarding the scope, construction, validity, and enforceability of any Patent Rights or trademark rights relating to a Licensed Product will be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent or trademark Laws of the country in which such Patent Right or trademark was granted or arose.

12.4 Assignment.

Except as provided in this Section 12.4, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may, without the other Party's written consent, assign or otherwise transfer this Agreement and its rights and obligations hereunder in whole or in part to (a) an Affiliate of such Party, or (b) a to a successor in interest by way of merger, consolidation, sale of stock or sale of all or substantially all of the assets of such Party to which this Agreement relates. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Any assignment not in compliance with this Section 12.4 shall be void.

12.5 Entire Agreement; Amendments.

This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, including the Confidentiality Agreement. This Agreement (including the Exhibits hereto) may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties.

12.6 Notices.

All notices which are required or permitted hereunder shall be in writing and shall be deemed to have been duly delivered and received hereunder (a) three (3) Business Days after being sent by registered or certified mail, return receipt requested, postage prepaid, (b) two (2) Business Days after being sent for next Business Day delivery, fees prepaid, via a reputable international overnight courier service, or (c) immediately upon delivery by email, by hand or by facsimile, in each case to the intended recipient as set forth below (or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith):

Notices to Poseida shall be addressed to:

Poseida Therapeutics, Inc.  
9390 Towne Center Drive  
San Diego, CA 92121  
Attention: CEO & General Counsel  
Email: [...\*\*\*...]

With a copy to:

Cooley LLP  
Reston Town Center  
11951 Freedom Drive  
14th Floor  
Reston, VA 20190-5640  
Attention: Kenneth Krisko  
Email: [...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

Notices to Takeda shall be addressed to:

Takeda Pharmaceuticals USA, Inc.  
95 Hayden Avenue  
Lexington, MA 02421  
Attention: Head of R&D Legal  
Email: [...\*\*\*...]

12.7 Force Majeure.

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from unforeseeable epidemics, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts, fire, floods, or acts, omissions or delays in acting by any Governmental Authority or the other Party. For the avoidance of doubt, the Parties agree that the effects of the COVID-19 pandemic that is ongoing as of the Effective Date shall not be deemed unforeseeable or invoked as a force majeure hereunder. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

12.8 No Strict Construction.

This Agreement has been prepared jointly and shall not be strictly construed against any Party.

12.9 Headings.

The captions or headings of the Sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.

12.10 No Implied Waivers; Rights Cumulative.

No failure on the part of Poseida or Takeda to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at Law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

12.11 Severability.

If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions best reflect the original intent of the Parties and in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalid, illegal or unenforceable of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.

12.12 Interpretation.

Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and

\*\*\* Certain Confidential Information Omitted

“including” shall be deemed to be followed by the phrase “without limitation.” The word “will” shall be construed to have the same meaning and effect as the word “shall.” Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Laws herein shall be construed as referring to such Laws as they from time to time may be enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person’s successors and assigns, (d) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference herein to the words “mutually agree” or “mutual written agreement” shall not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party’s sole discretion, (f) all references herein to Articles, Sections, or Exhibits shall be construed to refer to Articles, Sections and Exhibits of this Agreement, (g) the word “or” shall be construed to have the same meaning and effect as “and/or” unless the context dictates otherwise because the subjects of the conjunction are mutually exclusive, (h) a term not defined herein but reflecting a different part of speech than a term which is defined herein shall be interpreted in a correlative manner, (i) any reference in this Agreement to a “day” or a number of “days” (without explicit reference to “Business Days”) shall be interpreted as a reference to a calendar day or number of calendar days, and (j) if the last day for the exercise of any privilege or the discharge of any duty under this Agreement falls upon a day which is not a Business Day, then the Party having such privilege or duty will have until the end of the next succeeding regular Business Day to exercise such privilege or to discharge such duty. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control. [...\*\*\*...] shall not constitute an active ingredient for the purposes of Section 1.1.20, Section 1.1.33 and Section 1.1.99.

12.13 Relationship of the Parties.

It is expressly agreed that Poseida and Takeda are independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture, or agency, including for Tax purposes. Neither Poseida nor Takeda will have the authority to make any statements, representations, or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party. Nothing contained in this Agreement shall be deemed to make any member of the JSC or any subcommittee or project team a partner, agent, or legal representative of the other Party, or to create any fiduciary relationship for any purpose whatsoever. Except as may be explicitly provided in this Agreement, no member of the JSC or any subcommittee or project team will have any authority to act for, or to assume any obligation or responsibility on behalf of, any other member of the JSC, subcommittee or project team (as applicable) of the other Party.

12.14 Binding Effect; No Third Party Beneficiaries.

As of the Effective Date, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Except as expressly set forth in this Agreement, no Person other than the Parties and their respective Affiliates and permitted assigns shall be deemed an intended Third Party beneficiary hereunder or have any right to enforce any obligation of this Agreement.

\*\*\* Certain Confidential Information Omitted

12.15 Further Assurances.

Each Party agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such additional assignments, agreements, documents and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure of and confirm unto such other Party its rights and remedies under, this Agreement.

12.16 Counterparts; Electronic Signatures.

The Parties agree that each may execute this Agreement using electronic signatures. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures and signatures transmitted via PDF or electronic signatures shall be treated as original signatures.

*[Remainder of This Page Intentionally Left Blank]*

\*\*\* Certain Confidential Information Omitted

IN WITNESS WHEREOF, Poseida and Takeda have caused this Agreement to be duly executed by their authorized representatives, as of the Effective Date.

**POSEIDA THERAPEUTICS, INC.**

By: /s/ Eric M. Ostertag  
Name: Eric M. Ostertag, M.D., Ph.D.  
Title: Chief Executive Officer

*[Signature Page to Collaboration and License Agreement]*

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IN WITNESS WHEREOF, Poseida and Takeda have caused this Agreement to be duly executed by their authorized representatives, as of the Effective Date.

**TAKEDA PHARMACEUTICALS USA, INC.**

By: /s/ Nenad Grmusa

Name: Nenad Grmusa

Title: Head of Center for External Innovation

*[Signature Page to Collaboration and License Agreement]*

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Exhibit 1.1.53

Excluded In-License Agreements

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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Exhibit 1.1.59

**Final Data Package**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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Exhibit 1.1.72

In-License Agreements

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 1.1.114**

**Platform Evaluation Work Plan**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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Exhibit 1.1.124

**Poseida Platform Trademarks**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 1.1.125**

**Poseida Technology Platforms (as of the Effective Date)**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 1.1.141A**

**Hemophilia A Research Plan**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 1.1.141B**

**Phenylketonuria Research Plan**

See attached.

\*\*\* Certain Confidential Information Omitted

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[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 1.1.165**

[...\*\*\*...] **Indications**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 1.1.166**

[...\*\*\*...] **Indications**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 5.2(g)(i)**

**Relevant Terms of In-License Agreements**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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Exhibit 5.2(g)(iii)

**Relevant Terms of Excluded In-Licenses**

[...\*\*\*...]

\*\*\* Certain Confidential Information Omitted

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**Exhibit 8.2(b)**

**Form of Press Release**

**Poseida Therapeutics Announces Research Collaboration with Takeda for Novel Non-Viral In Vivo Gene Therapies**

*Collaboration to leverage Poseida's non-viral piggyBac® DNA Modification System, Cas-CLOVER™ Site-Specific Gene Editing System, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms*

*Collaboration to initially include up to six liver- and hematopoietic stem cell (HSC)- directed indications with an option to add two additional programs*

*In addition to an upfront payment, Poseida is eligible to receive preclinical, development and commercial milestone payments plus tiered royalties into the double digits*

*Poseida to host conference call today at 8:00am ET*

**SAN DIEGO Oct. 12, 2021**— Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced that it has entered into a research collaboration and exclusive license agreement with Takeda Pharmaceutical Company Limited (“Takeda”) to utilize Poseida’s piggyBac, Cas-CLOVER, biodegradable DNA and RNA nanoparticle delivery technology and other proprietary genetic engineering platforms for the research and development of up to eight gene therapies. The collaboration will focus on developing non-viral in vivo gene therapy programs, including Poseida’s Hemophilia A program.

“We are excited to partner with Takeda, a global biopharmaceutical leader whose commitment to the development of novel therapies for rare diseases complements our innovative platform technologies and robust gene therapy pipeline,” said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida. “Our technologies offer highly efficient gene delivery, fully integrated non-viral genome insertion and ultra-precise site-specific gene editing. Together with Takeda, we look forward to developing potential cures for a number of genetic diseases with high unmet need.”

Under the terms of the agreement, the parties will collaborate to initially develop up to six in vivo gene therapy programs utilizing Poseida’s novel technology platforms including piggyBac, Cas-CLOVER and biodegradable nanoparticle technology, as well as certain emerging technologies. Takeda also has an option to add two additional programs to the collaboration and is obligated to provide funding for all collaboration program R&D costs.

Poseida will receive an upfront payment of \$45 million and preclinical milestones that together could potentially exceed \$125 million in the aggregate, if milestones for six programs are achieved. Poseida is also eligible to receive future clinical development, regulatory, and commercial milestone payments with a total potential value over the course of the partnership of up to \$2.7 billion if milestones for all six programs are achieved, and up to \$3.6 billion if the milestones related to the two optional programs are also achieved. Poseida will lead research activities up to candidate

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selection, after which Takeda will assume responsibility for further development and commercialization.

“Poseida’s differentiated platform technologies show great promise in developing non-viral in vivo gene therapies using their novel genetic engineering and delivery technologies that complement our existing collaborations,” said Takeda Rare Diseases Drug Discovery Unit Head, Madhu Natarajan. “This partnership reinforces Takeda’s commitment to investing in next-generation gene therapy approaches that have the potential to deliver functional cures to patients with rare genetic and hematologic diseases. We look forward to partnering with Poseida where we can apply our broad development capabilities to help progress several early stage preclinical programs.”

#### **Poseida Therapeutics Conference Call and Webcast Information**

Poseida’s management team will host a conference call and webcast at 8:00am ET today, October 12, 2021 to discuss the collaboration. The dial-in numbers for domestic and international callers are (866) 939-3921 and (678) 302-3550, respectively. The conference ID number for the call is 50242119.

Participants may access the live webcast on the Investors & Media Section of the Poseida website, [www.poseida.com](http://www.poseida.com). An archived replay of the webcast will be available for approximately 30 days following the event.

#### **About Poseida Therapeutics, Inc.**

Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac DNA Modification System, Cas-CLOVER Site-Specific Gene Editing System and biodegradable nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics. To learn more, visit [www.poseida.com](http://www.poseida.com) and connect with us on [Twitter](#) and [LinkedIn](#).

#### **Forward-Looking Statement**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding potential payments and activities under the collaboration agreement with Takeda, the potential benefits of Poseida's technology platforms and product candidates and Poseida's plans and strategy with respect to developing its technologies and product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Poseida's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the fact that the collaboration agreement with Takeda may be terminated early, the fact that Poseida will have limited control over the efforts and resources that Takeda devotes to advancing development programs

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under the collaboration agreement, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry, the fact that future preclinical and clinical results could be inconsistent with results observed to date and the other risks described in Poseida's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Poseida undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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**Poseida Therapeutics Contacts:**

Marcy Graham  
VP, Corporate Affairs  
Poseida Therapeutics, Inc.  
858-779-3108  
[mgraham@poseida.com](mailto:mgraham@poseida.com)

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Director, Corporate Communications and IR  
Poseida Therapeutics  
858-605-3717  
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## LOAN AND SECURITY AGREEMENT

**THIS LOAN AND SECURITY AGREEMENT** (as the same may from time to time be amended, modified, supplemented or restated, this “**Agreement**”) dated as of February 22, 2022 (the “**Effective Date**”) among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, VA 22314 (“**Oxford**”), as collateral agent (in such capacity, “**Collateral Agent**”), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a “**Lender**” and collectively, the “**Lenders**”), and POSEIDA THERAPEUTICS, INC., a Delaware corporation with offices located at 9390 Towne Centre Drive, Suite 200, San Diego, California 92121 (“**Parent**”), VINDICO NANOBIO TECHNOLOGY, LLC, a Delaware limited liability company and a wholly owned subsidiary of Parent with offices located at 9390 Towne Centre Drive, Suite 200, San Diego, California 92121 (“**US Sub**”) (Parent and the US Sub, individually and collectively, jointly and severally, “**Borrower**”), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

**1. ACCOUNTING AND OTHER TERMS**

**1.1** Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 1.3. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to “**Dollars**” or “**\$**” are United States Dollars, unless otherwise noted.

**2. LOANS AND TERMS OF PAYMENT**

**2.1** **Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

**2.2** **Term Loans.**

(a) **Availability.** Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate amount of Sixty Million Dollars (\$60,000,000.00) according to each Lender’s Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “**Term Loan**”, and collectively as the “**Term Loans**”). After repayment, no Term Loan may be re-borrowed.

(b) **Repayment.** Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender’s Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (i) twenty-three (23) months, if the Equity Event does not occur and (ii) eleven (11) months, if the Equity Event occurs. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) **Mandatory Prepayments.** If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders’ Expenses and interest at the Default Rate with respect

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to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).

(d) Permitted Prepayment of Term Loans.

(i) Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

(ii) Notwithstanding anything herein to the contrary, Borrower shall also have the option to prepay part of Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, (ii) prepays such part of the Term Loans in a denomination that is a whole number multiple of Five Million Dollars (\$5,000,000.00), and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment, and (C) all other Obligations that are then due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts, and (D) the applicable Prepayment Fee with respect to the portion of such Term Loans being prepaid. For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under Section 2.2(b) on a pro-rata basis.

**2.3 Payment of Interest on the Credit Extensions.**

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the Term Loans and then monthly thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 12:00 noon Eastern time are

considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

**2.4 Secured Promissory Notes.** The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a “**Secured Promissory Note**”), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender’s Secured Promissory Note, an appropriate notation on such Lender’s Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender’s Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender’s Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

**2.5 Fees.** Borrower shall pay to Collateral Agent:

- (a) Final Payment. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;
- (b) Prepayment Fee. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares; and
- (c) Lenders’ Expenses. All Lenders’ Expenses (including reasonable attorneys’ fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

**2.6 Withholding.** Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

### **3. CONDITIONS OF LOANS**

**3.1 Conditions Precedent to Initial Credit Extension.** Each Lender’s obligation to make the initial Credit Extension is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

- (a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;
- (b) subject to the terms of the Post Closing Letter, duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries;
- (c) duly executed original Secured Promissory Notes in favor of each Lender according to its Term Loan Commitment Percentage;
- (d) the certificate(s) for the Shares, together with Assignment(s) Separate from Certificate;
- (e) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency or registered office, as applicable) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;
- (f) a completed Perfection Certificate for Borrower and each of its Subsidiaries;
- (g) the Annual Projections, for the current calendar year;
- (h) duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;
- (i) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;
- (j) subject to the terms of the Post Closing Letter, a landlord's consent executed in favor of Collateral Agent in respect of all of Borrower's San Diego headquarters;
- (k) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;
- (l) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders;
- (m) a copy of any applicable Registration Rights Agreement or Investors' Rights Agreement and any amendments thereto;
- (n) a payoff letter from Oxford in respect of the Existing Indebtedness; and
- (o) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

**3.2 Conditions Precedent to all Credit Extensions.** The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

- (a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;
- (b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of

such date;

(c) in such Lender's sole and reasonable discretion, there has not been any Material Adverse Change;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

**3.3 Covenant to Deliver.** Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

**3.4 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon Eastern time three (3) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

#### **4. CREATION OF SECURITY INTEREST**

**4.1 Grant of Security Interest.** Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code) with a value in excess of \$100,000, Borrower, shall promptly notify Collateral Agent in a writing signed by Borrower, after Borrower becomes aware of such tort claim, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

**4.2 Authorization to File Financing Statements.** Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral,

without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

**4.3 Pledge of Collateral.** Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any Shares, the certificate or certificates for the Shares (if any) will be delivered to Collateral Agent, accompanied by an instrument of assignment or share transfer form duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books (or register of members, as applicable) of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

## **5. REPRESENTATIONS AND WARRANTIES**

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

**5.1 Due Organization, Authorization: Power and Authority.** Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization, incorporation or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each as updated from time to time, as permitted hereunder, a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational or registration number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

## 5.2 Collateral.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith (as the same may be updated from time to time, provided that any such updates shall be in form and substance acceptable to Collateral Agent and each Lender, in its sole discretion) with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein to the extent required by Section 6.6. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, except as disclosed on the Perfection Certificate on the Effective Date, (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of Five Hundred Thousand Dollars (\$500,000). None of the components of the Collateral with a value in excess of Five Hundred Thousand Dollars (\$500,000) shall be maintained at locations other than (i) as disclosed in the Perfection Certificates on the Effective Date, (ii) with contract manufacturers or at clinical sites, for so long as such Collateral constitutes of non-commercial clinical compounds, or as permitted pursuant to Section 6.11.

(c) All Inventory is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiaries' interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within ten (10) days of Borrower or any of its Subsidiaries entering into or becoming bound by any license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

**5.3 Litigation.** Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Five Hundred Thousand Dollars (\$500,000.00).

**5.4 No Material Deterioration in Financial Condition; Financial Statements.** All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the

consolidated results of operations of Borrower and its Subsidiaries as of the dates and for the periods presented. Lender understands that interim financial statements may not be audited and may be subject to normal year-end adjustments and the absence of footnotes. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries since the date of the most recent financial statements submitted to any Lender.

**5.5 Solvency.** (i) Parent is Solvent and (ii) Borrower and its Subsidiaries are Solvent, on a consolidated basis.

**5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an “investment company” or a company “controlled” by an “investment company” under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a “holding company” or an “affiliate” of a “holding company” or a “subsidiary company” of a “holding company” as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower’s nor any of its Subsidiaries’ properties or assets has been used by Borrower or such Subsidiary or, to Borrower’s knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower’s or its Subsidiaries’ Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

**5.7 Investments.** Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

**5.8 Tax Returns and Payments; Pension Contributions.** Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and material local taxes, assessments, deposits and contributions (i.e. local taxes, assessments, deposits and contributions in an aggregate amount of \$100,000 or more) owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the following sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a “**Permitted Lien.**” Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower’s or such Subsidiaries’, prior tax years which could result in additional taxes becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**5.9 Use of Proceeds.** Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

**5.10 Shares.** Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement or any other applicable Loan Document. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

**5.11 Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

**5.12 Definition of "Knowledge."** For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

## **6. AFFIRMATIVE COVENANTS**

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

### **6.1 Government Compliance.**

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

### **6.2 Financial Statements, Reports, Certificates.**

(a) Deliver to each Lender:

(i) no later than thirty (30) days after the last day of each month, a company prepared consolidated balance sheet, income statement and cash flow statement covering the consolidated operations of Parent and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) no later than ninety (90) days after the last day of Parent's fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently

applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion (other than any "going concern" solely in connection with the need to raise equity and negative profits);

(iii) no later than sixty (60) days after the last day of Parent's fiscal years, Parent's annual financial projections for the entire current fiscal year as approved by Parent's Board of Directors, which such annual financial projections shall be set forth in a quarter-by-quarter format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the "Annual Projections"; provided that, any revisions of the Annual Projections approved by Parent's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) days of delivery, copies of all statements, reports and notices made available to Borrower's security holders or holders of Subordinated Debt;

(v) within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission;

(vi) prompt notice of any changes to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s); and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing.

(d) Deliver to Collateral Agent and Alexandria Real Estate, no later than thirty (30) days after the last day of each month in which Borrower has delivered in excess of One Hundred Thousand Dollars (\$100,000) worth of new Collateral to the property located at 4242 Campus Point Court, San Diego, California, an updated, fully comprehensive, Exhibit A to the landlord lien waiver among Alexandria Real Estate, Heron Therapeutics, Inc., Borrower and Collateral Agent (the "ARE Waiver").

**6.3 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than Five Hundred Thousand Dollars (\$500,000.00) individually or in the aggregate in any calendar year.

**6.4 Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports or extensions therefor (which are timely filed and accepted and approved by the applicable Governmental Authority) and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and material local taxes, assessments, deposits and contributions (i.e. local taxes, assessments, deposits and contributions in an aggregate amount of \$100,000 or more) owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

**6.5 Insurance.** Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Five Hundred Thousand Dollars (\$500,000.00) with respect to any loss, but not exceeding Five Hundred Thousand Dollars (\$500,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

**6.6 Operating Accounts.**

(a) Maintain all of Borrower's Collateral Accounts in accounts which are subject to a Control Agreement in favor of Collateral Agent, which Control Agreement must be in such form and substances as is reasonably acceptable to Collateral Agent.

(b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account. In addition, for each Collateral Account that Borrower at any time maintains, Borrower shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement must be in such form and substance as is reasonably satisfactory to Collateral Agent and may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence and subsection (a) above shall not apply to (i) deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit

of Borrower's employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates and (ii) BofA Credit Card Account so long as such account is maintained exclusively for the purpose of securitizing Borrower's Indebtedness described in clause (g) of the definition of Permitted Indebtedness and the balance in such account does not exceed Three Hundred One Thousand Dollars (\$301,000.00).

(c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

**6.7 Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

**6.8 Litigation Cooperation.** Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

**6.9 Notices of Litigation and Default.** Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Five Hundred Thousand Dollars (\$500,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

**6.10 Landlord Waivers; Bailee Waivers.** In the event that Borrower or any of its Subsidiaries that are Loan Parties, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral constituting of the books and records of the Borrower or any of its Subsidiaries or having an aggregate book value in excess of Five Hundred Thousand Dollars (\$500,000.00) (other than with contract manufacturers or at clinical sites, in which case the Collateral must comprise only of non-commercial clinical compounds), or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Loan Party will first notify Collateral Agent in advance and, in the event that the new location is the chief executive office of the Borrower or such Loan Party or the Collateral at any such new location is valued in excess of exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate or constituting of the books and records of the Borrower or any Loan Party, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new officers or business locations, or any such storage with or delivery to any such bailee, as the case may be. Notwithstanding the foregoing, the ARE Waiver shall still be required.

**6.11 Creation/Acquisition of Subsidiaries.** In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares; provided, however, that solely in the circumstance in which Borrower or any Subsidiary creates or acquires a Foreign Subsidiary in an acquisition permitted by Section 7.7 hereof or otherwise approved by the

Required Lenders, (i) such Foreign Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents and grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary, and (ii) Borrower shall not be required to grant and pledge to Collateral Agent, for the ratable benefit of Lenders, a perfected security interest in more than sixty-five percent (65%) of the Shares of such Foreign Subsidiary, if Borrower demonstrates to the reasonable satisfaction of Collateral Agent that such Foreign Subsidiary providing such guarantee or pledge and security interest or Borrower providing a perfected security interest in more than sixty-five percent (65%) of the Shares would create a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code.

#### 6.12 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.

#### 7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

**7.1 Dispositions.** Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out, surplus or obsolete Equipment; and (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) from any Subsidiary of Borrower to Borrower or between Borrowers; (e) of cash and Cash Equivalents in connection with transactions not prohibited hereunder, in the ordinary course of business and approved by the Borrower's Board of Directors or consistent with the then applicable Annual Projections; and (f) other Transfers of property having a book value not exceeding exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate during any fiscal year.

**7.2 Changes in Business, Management, Ownership, or Business Locations.** (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate, wind-up or dissolve; provided that any Subsidiary of the Borrower may liquidate, wind-up or dissolve itself as long as all of its assets are transferred to the Borrower or a secured Guarantor; or (c) (i) any Key Person shall cease to be employed by, or actively engaged in the management of, Borrower unless written notice thereof is provided to Collateral Agent within five (5) days of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction) ("**Change of Control**"). Borrower shall not, without at least thirty (30) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (i) contain less than Five Hundred Thousand Dollars (\$500,000.00) in assets or property of Borrower or its Subsidiaries, (ii) do not contain any books or records of Borrower or its Subsidiaries, (iii) are not Borrower's or its Subsidiaries' chief executive office and (iv) such new locations contain only non-commercial clinical compounds); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

**7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person other than pursuant to a Permitted Investment. A Subsidiary

may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

**7.4 Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

**7.5 Encumbrance.** Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" herein.

**7.6 Maintenance of Collateral Accounts.** Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

**7.7 Distributions; Investments.** (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock or share capital except that Borrower or any Subsidiary may (i) repurchase the stock of current or former employees, officers, directors or consultants so long as such repurchases do not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate per fiscal year (ii) repurchase stock pursuant to the right of first refusal pursuant to Parent's bylaws, so long as such repurchases do not exceed Two Hundred Fifty Thousand Dollars (\$250,000) in the aggregate per fiscal year, (iii) repurchase the stock of current or former employees, officers, directors or consultants pursuant to stock repurchase agreements by the cancellation of indebtedness owed by such former employees provided that the aggregate amount of indebtedness cancelled pursuant to this clause (iii) does not exceed Two Hundred Fifty Thousand Dollars (\$250,000) per fiscal year, (iv) make cash payments in lieu of the issuance of fractional shares upon conversion of convertible securities so long as the aggregate amount of such cash payments does not exceed Ten Thousand Dollars (\$10,000.00) in any given fiscal year or (v) convert or exchange any of its convertible securities into or for other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof; or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so. For the sake of clarity, Parent's payments to its Subsidiaries for services performed by such Subsidiaries for Borrower in accordance with Section 7.8 are not prohibited under this Agreement because they are not deemed Investments.

**7.8 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, (c) any transaction expressly allowed under Section 7.1, (d) compensation and indemnification of, and other employment arrangements with, directors, officers and employees of Borrower or any Subsidiary, in each case, entered into in the ordinary course of business in accordance with Borrower's Annual Projections and corporate governance practices, (e) loans and advances otherwise explicitly permitted hereunder to be made to the applicable Affiliate and (f) transactions disclosed in the Borrower's Perfection Certificates on the Effective Date (and without any amendments to the terms of such transactions which amendments would constitute such incremental or new transactions as would require consent of the Required Lenders or Collateral Agent hereunder).

**7.9 Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

**7.10 Compliance.** Become an “investment company” or a company controlled by an “investment company”, under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**7.11 Compliance with Anti-Terrorism Laws.** Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent’s policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

## **8. EVENTS OF DEFAULT**

Any one of the following shall constitute an event of default (an “**Event of Default**”) under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

### **8.2 Covenant Default.**

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time,

then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;

**8.3 Material Adverse Change.** A Material Adverse Change occurs;

**8.4 Attachment; Levy; Restraint on Business.**

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

**8.5 Insolvency.** (a) Borrower or, Borrower and its Subsidiaries on a consolidated basis, is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

**8.6 Other Agreements.** There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Five Hundred Thousand Dollars (\$500,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Collateral Agent or any Lender has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower;

**8.7 Judgments.** One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars (\$500,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

**8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

**8.9 Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

**8.10 Guaranty.** (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the death of a Guarantor who is a natural person, or the liquidation, winding up, or termination of existence of any Guarantor that is an entity;

**8.11 Governmental Approvals.** Any Governmental Approval issued shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or

**8.12 Lien Priority.** Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement.

**8.13 Delisting.** The shares of common stock of Borrower are delisted from the Nasdaq Global Select Market because of failure to comply with continued listing standards thereof or due to a voluntary delisting (other than pursuant to a Change of Control) which results in such shares not being contemporaneously listed on any other nationally recognized stock exchange in the United States having listing standards at least as restrictive as the Nasdaq Global Select Market.

## 9. RIGHTS AND REMEDIES

### 9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

- (i) foreclose upon and/or sell or otherwise liquidate, the Collateral;
- (ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or
- (iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

**9.2 Power of Attorney.** Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies;

(e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

**9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

**9.4 Application of Payments and Proceeds.** Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

**9.5 Liability for Collateral.** So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

**9.6 No Waiver; Remedies Cumulative.** Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

**9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

**10. NOTICES**

All notices, consents, requests, approvals, demands, or other communication (collectively, "Communication") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile or electronic mail transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address, facsimile number, or email address by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:

POSEIDA THERAPEUTICS, INC.  
VINDICO NANOBIO TECHNOLOGY, LLC  
9390 Towne Centre Drive, Suite 200, San Diego, California 92121  
Attn: Johanna Mylet  
Fax: (619) 780-2667  
Email: jmylet@poseida.com

with a copy (which shall not constitute notice) to:

Cooley LLP  
3 Embarcadero Center  
20th Floor  
San Francisco, CA 94111-4004  
Attn: Maricel Mojares-Moore  
Fax: (415) 693 2222  
Email: mmoore@cooley.com

If to Collateral Agent:

OXFORD FINANCE LLC  
115 South Union Street  
Suite 300  
Alexandria, VA 22314  
Fax: (703) 519-5225  
Email: LegalDepartment@oxfordfinance.com

with a copy (which shall not constitute notice) to:

Greenberg Traurig, LLP  
One International Place  
Boston, MA 02110  
Attn: Abdullah Malik  
Fax: (617) 897-0983  
Email: malikab@gtlaw.com

**11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER, AND JUDICIAL REFERENCE**

California law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Collateral Agent and each Lender each submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Agreement shall be deemed to preclude Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Collateral Agent or any Lender. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

**TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT AND EACH LENDER EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure §§ 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such

relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure § 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

## 12. GENERAL PROVISIONS

**12.1 Successors and Assigns.** This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided, however*, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "**Approved Lender**"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

**12.2 Indemnification.** Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

12.3 **Time of Essence.** Time is of the essence for the performance of all Obligations in this Agreement.

12.4 **Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.5 **Correction of Loan Documents.** Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.

12.6 **Amendments in Writing; Integration.** (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "**Required Lenders**" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations,

warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

**12.7 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

**12.8 Survival.** All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

**12.9 Confidentiality.** In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

**12.10 Right of Set Off.** Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

**12.11 Cooperation of Borrower.** If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of

information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

**12.12 Borrower Liability.** Either Borrower may, acting singly, request Credit Extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting Credit Extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all Credit Extensions made hereunder, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, including, without limitation, the benefit of California Civil Code Section 2815 permitting revocation as to future transactions and the benefit of California Civil Code Sections 1432, 2809, 2810, 2819, 2839, 2845, 2847, 2848, 2849, 2850, and 2899 and 3433, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

### 13. **DEFINITIONS**

**13.1 Definitions.** As used in this Agreement, the following terms have the following meanings:

**"Account"** is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

**"Account Debtor"** is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

**"Affiliate"** of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

**"Agreement"** is defined in the preamble hereof.

**"Alexandria Real Estate"** means ARE-SD REGION NO. 61, LLC, a Delaware limited liability company.

**"Amortization Date"** is, (i) April 1, 2025, if the Equity Event does not occur, and (ii) April 1, 2026, if the Equity Event occurs.

**"Annual Projections"** is defined in Section 6.2(a).

“**Anti-Terrorism Laws**” are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

“**Approved Fund**” is any (a) Person, investment company, fund, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business and that is administered or managed by (i) a Lender, (ii) an Affiliate of a Lender, or (iii) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender, or (b) any Person (other than a natural person) which temporarily warehouses loans, or provides financing or securitizations, in each case, for any Lender or any entity described in the preceding clause (a).

“**Approved Lender**” is defined in Section 12.1.

“**Basic Rate**” is, with respect to a Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the greater of (i) seven and ninety-four hundredths percent (7.94%) and (ii) the sum of (a) the thirty (30) day U.S. LIBOR rate reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue, plus (b) seven and eighty-three hundredths percent (7.83%). Notwithstanding the foregoing, the Basic Rate for the Term Loan for the period from the Effective Date through and including February 28, 2022 shall be seven and ninety-four hundredths percent (7.94%). Notwithstanding anything to the contrary herein or in any other Loan Document, upon the occurrence of a LIBOR Transition Event, Collateral Agent may amend this Agreement to replace the Basic Rate with a LIBOR Replacement Rate. Any such amendment with respect to a LIBOR Transition Event will become effective at 5:00 p.m. (Eastern Standard Time) on the third Business Day after Collateral Agent has notified Borrower of such amendment. Any determination, decision or election that may be made by Collateral Agent pursuant hereto will be conclusive and binding absent manifest error and may be made in Collateral Agent’s sole discretion and without consent from any other party.

“**Blocked Person**” is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“**BofA Credit Card Account**” is Borrower’s account numbered \*\*\*\*\*2921 maintained with Bank of America exclusively for the purposes of securitizing the Borrower’s Indebtedness described in clause (g) of the definition of Permitted Indebtedness.

“**Borrower**” is defined in the preamble hereof.

“**Borrower’s Books**” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“**Business Day**” is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

“**Cash Equivalents**” are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor’s Ratings Group or Moody’s Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction

Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an "**Auction Rate Security**").

"**Claims**" are defined in Section 12.2.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

"**Collateral Agent**" is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

"**Commitment Percentage**" is set forth in Schedule 1.1, as amended from time to time.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"**Communication**" is defined in Section 10.

"**Compliance Certificate**" is that certain certificate in the form attached hereto as Exhibit C.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the

meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

“**Copyrights**” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“**Credit Extension**” is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower’s benefit.

“**Default Rate**” is defined in Section 2.3(b).

“**Deposit Account**” is any “deposit account” as defined in the Code with such additions to such term as may hereafter be made.

“**Designated Deposit Account**” is Borrower’s deposit account, account number x-5888, maintained with Bank of America.

“**Disbursement Letter**” is that certain form attached hereto as Exhibit B.

“**Dollars,**” “**dollars**” and “**\$**” each mean lawful money of the United States.

“**Effective Date**” is defined in the preamble of this Agreement.

“**Eligible Assignee**” is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an “accredited investor” (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor’s Rating Group and a rating of Baa2 or higher from Moody’s Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars (\$5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, “Eligible Assignee” shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower’s Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender’s own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

“**Equipment**” is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

“**Equity Event**” is the receipt by Borrower on or after the Effective Date and on or before March 31, 2025, of unrestricted net cash proceeds of not less than One Hundred Fifty Million Dollars (\$150,000,000.00) from (i) the issuance and sale by Borrower of its equity securities and/or (ii) “up front” or milestone payments in connection with a joint venture, collaboration or other partnering transaction.

“ERISA” is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

“Event of Default” is defined in Section 8.

“Existing Indebtedness” is the indebtedness of Borrower to Oxford in the aggregate principal outstanding amount as of the Effective Date of approximately Thirty Million Dollars (\$30,000,000.00) pursuant to that certain Loan and Security Agreement, dated July 25, 2017, entered into by and between Oxford, other lenders party thereto from time to time and Borrower.

“Federal Reserve Bank of New York’s Website” means the website of the Federal Reserve Bank of New York at <http://www.newyorkfed.org>, or any successor source.

“Final Payment” is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan funded multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares. For the avoidance of doubt, the calculation of any Final Payment shall not include the principal amount prepaid in accordance with Section 2.2(d)(ii) if a Final Payment based on such principal amount was made at the time of such prepayment.

“Final Payment Percentage” is seven and fifty hundredths percent (7.50%).

“Foreign Subsidiary” is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

“Funding Date” is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

“GAAP” is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

“General Intangibles” are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

“Governmental Approval” is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

“Governmental Authority” is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

“Guarantor” is any Person providing a Guaranty in favor of Collateral Agent.

“**Guaranty**” is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

“**Indebtedness**” is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations (excluding real property operating leases), and (d) Contingent Obligations.

“**Indemnified Person**” is defined in Section 12.2.

“**Insolvency Proceeding**” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

“**Insolvent**” means not Solvent.

“**Intellectual Property**” means all of Borrower’s or any Subsidiary’s right, title and interest in and to the following:

- (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;
- (c) any and all source code;
- (d) any and all design rights which may be available to Borrower;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
- (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

“**Inventory**” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“**Investment**” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

“**Key Person**” is each of Borrower’s (i) Chief Executive Officer, who is Mark J. Gergen as the Effective Date and (ii) Chief Financial Officer, who is Johanna Mylet as of the Effective Date.

“**Lender**” is any one of the Lenders.

“**Lenders**” are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

“**Lenders’ Expenses**” are all audit fees and expenses, costs, and expenses (including reasonable attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without

limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

**“LIBOR Replacement Rate”** means the sum of: (a) the alternate benchmark rate (which may include SOFR) that has been selected by Collateral Agent giving due consideration to (i) any selection or recommendation of a replacement rate or the mechanism for determining such a rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a rate of interest as a replacement to the LIBOR rate for U.S. dollar-denominated syndicated credit facilities and (b) the LIBOR Replacement Spread; provided that, if the LIBOR Replacement Rate as so determined would be less than zero, the LIBOR Replacement Rate will be deemed to be zero for the purposes of this Agreement.

**“LIBOR Replacement Spread”** means, with respect to any replacement of the Basic Rate, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative value or zero) that has been selected by Collateral Agent giving due consideration to (i) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate for U.S. dollar-denominated syndicated credit facilities at such time.

**“LIBOR Transition Event”** means the occurrence of one or more of the following events with respect to the LIBOR rate:

(1) a public statement or publication of information by or on behalf of the administrator of the LIBOR rate announcing that such administrator has ceased or will cease to provide the LIBOR rate, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate;

(2) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the administrator for the LIBOR rate, a resolution authority with jurisdiction over the administrator for the LIBOR rate or a court or an entity with similar insolvency or resolution authority over the administrator for the LIBOR rate, which states that the administrator of the LIBOR rate has ceased or will cease to provide the LIBOR rate permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate; or

(3) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate announcing that the LIBOR rate is no longer representative.

**“Lien”** is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

**“Loan Documents”** are, collectively, this Agreement, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the Post Closing Letter, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

**“Loan Party”** means Borrower and each Subsidiary that becomes a Guarantor.

**“Material Adverse Change”** is (a) a material impairment in the perfection or priority of Collateral Agent’s Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or Borrower and its Subsidiaries on a consolidated basis; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

**“Maturity Date”** is, for each Term Loan, February 1, 2027.

“**Obligations**” are all of Borrower’s obligations to pay when due any debts, principal, interest, Lenders’ Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents (other than the Warrants), or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower’s duties under the Loan Documents (other than the Warrants).

“**OFAC**” is the U.S. Department of Treasury Office of Foreign Assets Control.

“**OFAC Lists**” are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

“**Operating Documents**” are, for any Person, such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto and (d) if such Person is an exempted company, its certificate of incorporation, statutory registers, and memorandum and articles of association.

“**Patents**” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

“**Payment Date**” is the first (1<sup>st</sup>) calendar day of each calendar month, commencing on April 1, 2022.

“**Perfection Certificate**” and “**Perfection Certificates**” is defined in Section 5.1.

“**Permitted Indebtedness**” is:

- (a) Borrower’s Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;
- (e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);
- (f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower’s business;
- (g) Indebtedness with respect to corporate credit cards issued Bank of America (for the Borrower or any Subsidiary) in an aggregate amount outstanding at any time not to exceed Three Hundred Thousand Dollars (\$300,000.00);

(h) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect Borrower or a Subsidiary against fluctuation in interest rates, currency exchange rates or commodity prices; provided the aggregate amount of Indebtedness under this clause (h) may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any given time;

(i) Indebtedness in respect of letters of credit, bank guarantees and similar instruments issued for the account of the Borrower or any Subsidiary in the ordinary course of business supporting obligations under (A) workers' compensation, unemployment insurance and other social security laws and (B) bids, trade contracts, leases, statutory obligations, surety and appeal bonds, performance bonds and obligations of a like nature; provided the aggregate amount of Indebtedness under this clause (i) may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any given time

(j) Indebtedness constituting or consisting of Investments under clause (f) of the definition of "Permitted Investments" but without duplication;

(k) Other unsecured Indebtedness not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate at any time; and

(l) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (k) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

**"Permitted Investments" are:**

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any other Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent (and Collateral Agent acknowledges the investment policy delivered on or prior to the Effective Date is hereby approved);

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of deposit, securities and/or commodities accounts in which Collateral Agent has a perfected security interest (and which, in case of the securities and commodities accounts are maintained in accordance with Borrower's Investment Policy);

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments (i) by Borrower or any Subsidiary in Subsidiaries that are not Loan Parties, provide that the aggregate amount of all such Investments does not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate in any fiscal year; and (ii) by Borrower or any Subsidiary in or to any Loan Party;

(g) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors; not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(h) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(j) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support

(k) Investments constituting interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect Borrower or a Subsidiary against fluctuation in interest rates, currency exchange rates or commodity prices; provided, that the aggregate amount of Investments allowed under this clause (k) shall not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in any given fiscal year;

(l) Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business, provided that any cash investments by Borrower do not exceed Two Hundred Thousand Dollars (\$250,000) in the aggregate in any fiscal year; and

(m) other Investments not otherwise permitted herein provided that the aggregate amount of all such Investments in any year shall not exceed Five Hundred Thousand Dollars (\$500,000.00).

**"Permitted Licenses"** are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

**"Permitted Liens"** are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) Liens securing Indebtedness permitted under clause (e) of the definition of **"Permitted Indebtedness,"** provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within ninety (90) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the

aggregate amount not to exceed Five Hundred Thousand Dollars (\$500,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(g) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(h) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(i) Liens consisting of Permitted Licenses;

(j) easements, reservations, rights-of-way, restrictions, minor defects or irregularities in title and other similar Liens affecting real property not interfering in any material respect with the ordinary course of the business of Borrower;

(k) deposits to secure the performance of bids, trade contracts (other than for borrowed money), contracts for the purchase of property permitted hereunder, statutory obligations, surety and appeal bonds, performance bonds and other obligations of a like nature, in each case, incurred in the ordinary course of business not representing an obligation for borrowed money; provided, however, the aggregate amount of such deposits at any given time may not exceed Two Million Five Hundred Thousand Dollars (\$2,500,000.00);

(l) Liens in favor of customs and revenue authorities arising as a matter of law, in the ordinary course of Borrower's business, to secure payment of customs duties in connection with the importation of goods; provided, however, the aggregate amount of Indebtedness secured by such Liens may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any given time;

(m) (i) Liens on the BofA Credit Card Account to secure the Permitted Indebtedness described in clause (g) of the definition of Permitted Indebtedness and (ii) Liens on cash collateral securing letters of credit (maintained in a segregated bank account identified to the Collateral Agent in the Perfection Certificate) permitted by clause (i) of the definition of Permitted Indebtedness;

(n) Liens or deposits to secure the performance of leases incurred in the ordinary course of business and not representing an obligation for borrowed money and Liens to secure tenant improvements, provided the lessor thereof has executed a landlord consent in favor of, and in form and content reasonably acceptable to, Collateral Agent; provided, however, the sum of the aggregate amount of the Indebtedness secured by such Liens and the aggregate amount of such deposits at any given time may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00); and

(o) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (m), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien.

“**Person**” is any individual, sole proprietorship, partnership, limited liability company, exempted company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

“**Post Closing Letter**” is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

“**Prepayment Fee**” is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, one percent (1.00%) of the principal amount of such Term Loan prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, one percent (1.00%) of the principal amount of the Term Loans prepaid; and

(iii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan no Prepayment Fee shall be due.

“**Pro Rata Share**” is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

“**Registered Organization**” with respect to the Parent and the US Sub, is any “registered organization” as defined in the Code with such additions to such term as may hereafter be made.

“**Relevant Governmental Body**” means the Federal Reserve Board and/or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York or any successor thereto.

“**Required Lenders**” means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an “**Original Lender**”) have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender’s interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

“**Requirement of Law**” is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

“**Responsible Officer**” is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone, to the extent such Borrower has such officers.

“**Secured Promissory Note**” is defined in Section 2.4.

“**Secured Promissory Note Record**” is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

“**Securities Account**” is any “securities account” as defined in the Code with such additions to such term as may hereafter be made.

“**Shares**” is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower’s Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent’s reasonable satisfaction, that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary which is a Foreign Subsidiary, creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code, “Shares” shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

“**Solvent**” is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities (excluding any amounts booked as a liability related to the CIRM grants not to exceed \$23,700,000 in the aggregate); such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

“**SOFR**” with respect to any day means the secured overnight financing rate published for such day by the Federal Reserve Bank of New York, as the administrator of the benchmark, (or a successor administrator) on the Federal Reserve Bank of New York’s Website.

“**Subordinated Debt**” is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

“**Subsidiary**” is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

“**Term Loan**” is defined in Section 2.2(a) hereof.

“**Term Loan Commitment**” is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1. “**Term Loan Commitments**” means the aggregate amount of such commitments of all Lenders.

“**Trademarks**” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

“**Transfer**” is defined in Section 7.1.

“**Warrants**” are those certain Warrants to Purchase Stock dated as of the July 25, 2017, or any date thereafter, issued by Borrower in favor of each Lender or such Lender’s Affiliates.

**[Balance of Page Intentionally Left Blank]**

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

**BORROWER:**

POSEIDA THERAPEUTICS, INC.

By /s/ Johanna Mylet  
Name: Johanna Mylet  
Title: Chief Financial Officer

VINDICO NANOBIO TECHNOLOGY, LLC

By /s/ Johanna Mylet  
Name: Johanna Mylet  
Title: Chief Financial Officer

**COLLATERAL AGENT AND LENDER:**

OXFORD FINANCE LLC

By /s/ Colette H. Featherly  
Name: Colette H. Featherly  
Title: Senior Vice President

*[Signature Page to Loan and Security Agreement]*

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SCHEDULE 1.1

Lenders and Commitments

<b>Lender</b>	<b>Term Loan Commitment</b>	<b>Commitment Percentage</b>
OXFORD FINANCE LLC	\$60,000,000.00	100.00%
<b>TOTAL</b>	<b>\$60,000,000.00</b>	<b>100.00%</b>

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## EXHIBIT A

### Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) more than 65% of the total combined voting power of all classes of stock entitled to vote the shares of capital stock (the "Shares") of any Foreign Subsidiary, if Borrower demonstrates to Collateral Agent's reasonable satisfaction that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code; the (iii) BofA Credit Card Account and (iv) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral."

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property except as otherwise permitted by the Loan Agreement.

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**EXHIBIT B**

**Form of Disbursement Letter**

[see attached]

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**DISBURSEMENT LETTER**

[DATE]

The undersigned, being the duly elected and acting \_\_\_\_\_ of POSEIDA THERAPEUTICS, INC., a Delaware corporation with offices located at 9390 Towne Centre Drive, Suite 200, San Diego, California 92121 on behalf of itself and each other Borrower under the Loan Agreement (as defined below) (individually and collectively, jointly and severally, "**Borrower**"), does hereby certify to **OXFORD FINANCE LLC** ("**Oxford**" and "**Lender**"), as collateral agent (the "**Collateral Agent**") and in connection with that certain Loan and Security Agreement dated as of February 22, 2022, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.
2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.
5. No Material Adverse Change has occurred.
6. The undersigned is a Responsible Officer.

*[Balance of Page Intentionally Left Blank]*

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7. The proceeds of the Term Loan shall be disbursed as follows:

**Disbursement from Oxford:**

Loan Amount \$ \_\_\_\_\_

Less:

--Facility Fee (\$ \_\_\_\_\_)

--Existing Debt Payoff to be remitted to Oxford Finance LLC per the Payoff Letter dated February [ ], 2022 (\$ \_\_\_\_\_)

[--Interim Interest (\$ \_\_\_\_\_)]

--Lender's Legal Fees (\$ \_\_\_\_\_)\*

**Net Proceeds due from Oxford:** \$ \_\_\_\_\_

**TOTAL TERM LOAN NET PROCEEDS FROM LENDERS** \$ \_\_\_\_\_

\* Legal fees and costs are through the Effective Date. Postclosing legal fees and costs, payable after the Effective Date, to be invoiced and paid postclosing.

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8. The Term Loan shall amortize in accordance with the Amortization Table attached hereto.

9. The aggregate net proceeds of the Term Loans shall be transferred to the Designated Deposit Account as follows:

Account Name: [BORROWER]  
Bank Name: [\_\_\_\_\_]   
Bank Address: [\_\_\_\_\_]   
Account Number: \_\_\_\_\_  
ABA Number: [\_\_\_\_\_]

***[Balance of Page Intentionally Left Blank]***

Dated as of the date first set forth above.

**BORROWER:**

POSEIDA THERAPEUTICS, INC., on behalf of  
itself and all other Borrowers

By  
Name:  
Title:

**COLLATERAL AGENT AND LENDER:**

OXFORD FINANCE LLC

By  
Name:  
Title:

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**AMORTIZATION TABLE**  
(Term Loan)

[see attached]

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EXHIBIT C

Exhibit C

**Compliance Certificate**

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender  
FROM: POSEIDA THERAPEUTICS, INC., on behalf of itself and all other Borrowers

The undersigned authorized officer (“**Officer**”) of POSEIDA THERAPEUTICS, INC., on behalf of itself and all other Borrowers under and as defined in the Loan Agreement (as defined herein below) (individually and collectively, jointly and severally, “**Borrower**”), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the “**Loan Agreement**,” capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending \_\_\_\_\_ with all required covenants except as noted below;

(b) There are no Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower’s Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower’s Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

**Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under “Complies” column.**

Reporting Covenant	Requirement	Actual	Complies		
Financial statements	Monthly within 30 days		Yes	No	N/A

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Annual (CPA audited) statements	Within 90 days after FYE	YesNoN/A
Annual Financial Projections/Budget prepared on a quarterly basis)	Annually (within 60 days of FYE), and when revised	YesNoN/A
R & A/P agings	If applicable	YesNoN/A
10-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing	YesNoN/A
Compliance Certificate	Monthly within 30 days	YesNoN/A
' Report	When required	YesNoN/A
Total amount of Borrower's cash and cash equivalents at the end of the measurement period		\$ _____ YesNoN/A
Total amount of Borrower's Subsidiaries' cash and cash equivalents at the end of the measurement period		\$ _____ YesNoN/A
Updated Exhibit A Landlord Waiver	Within 30 days of each month during which new Collateral in excess of \$100,000 was delivered to 4242 Campus Point Court, San Diego, California	YesNoN/A

**Deposit and Securities Accounts**  
*(Please list all accounts; attach separate sheet if additional space needed)*

Institution Name	Account Number	New Account?		Account Control Agreement in place?	
		Yes	No	Yes	No
		Yes	No	Yes	No
		Yes	No	Yes	No
		Yes	No	Yes	No
		Yes	No	Yes	No

**Other Matters**

Have there been any changes in management since the last Compliance Certificate?	Yes	No
Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
Have there been any new or pending claims or causes of action against Borrower that involve more than Five Hundred Thousand Dollars (\$500,000.00)?	Yes	No

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Have there been any amendments of or other changes to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.

Yes

No

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**Exceptions**

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

POSEIDA THERAPEUTICS, INC., on behalf of itself and all other Borrowers

By  
Name:  
Title:  
Date:

**LENDER USE ONLY**

Received by: Date:

Verified by: Date:

Compliance Status: YesNo

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**EXHIBIT D**

**Form of Secured Promissory Note**

[see attached]

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**SECURED PROMISSORY NOTE  
(Term Loan)**

\$ \_\_\_\_\_ Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, POSEIDA THERAPEUTICS, INC., a Delaware corporation with offices located at 9390 Towne Centre Drive, Suite 200, San Diego, California 92121 and VINDICO NANOBIO TECHNOLOGY, LLC, a Delaware limited liability company with offices located at 9390 Towne Centre Drive, Suite 200, San Diego, California 921214 (individually and collectively, jointly and severally, "**Borrower**") HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("**Lender**") the principal amount of [ \_\_\_\_\_ ] MILLION DOLLARS (\$ \_\_\_\_\_) or such lesser amount as shall equal the outstanding principal balance of the Term Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated February 22, 2022 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term Loan, interest on the Term Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of California.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

*[Balance of Page Intentionally Left Blank]*

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IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

**BORROWER:**

POSEIDA THERAPEUTICS, INC.

By  
Name:  
Title:

VINDICO NANOBIO TECHNOLOGY, LLC

By  
Name:  
Title:

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LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	<u>Principal Amount</u>	Interest Rate	<u>Scheduled Payment Amount</u>	Notation By
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**CORPORATE BORROWING CERTIFICATE**

**BORROWER:** [BORROWER]  
**LENDER:** OXFORD FINANCE LLC, as Collateral Agent and Lender

**DATE:** [DATE]

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
2. Borrower's exact legal name is set forth above. Borrower is a [BORROWER ORGANIZATION] existing under the laws of the State of [BORROWER STATE].
3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's [Articles/Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above]; and (ii) Borrower's [Bylaws] [Memorandum and Articles of Association]. Neither such Articles/Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

*[Balance of Page Intentionally Left Blank]*

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RESOLVED, that any one of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name

Title

Signature

RESOLVED FURTHER, that any one of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

**Borrow Money.** Borrow money from the Lenders.

**Execute Loan Documents.** Execute any loan documents any Lender requires.

**Grant Security.** Grant Collateral Agent a security interest in any of Borrower's assets.

**Negotiate Items.** Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

**Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

*[Balance of Page Intentionally Left Blank]*

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5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

**By:**

**Name:**

**Title:**

*\*\*\* If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the \_\_\_\_\_ of Borrower, hereby certify as to paragraphs 1 through 5 above, as  
[print title]  
of the date set forth above.

**By:**

**Name:**

**Title:**

*[Signature Page to Corporate Borrowing Certificate]*

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**EXHIBIT A**

**Articles/Certificate of Incorporation (including amendments)**

[see attached]

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**EXHIBIT B**

**Bylaws**

[see attached]

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**DEBTOR:** [BORROWER]  
**SECURED PARTY:** OXFORD FINANCE LLC,  
as Collateral Agent

**EXHIBIT A TO UCC FINANCING STATEMENT**

**Description of Collateral**

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) more than 65% of the total combined voting power of all classes of stock entitled to vote the shares of capital stock (the "Shares") of any Foreign Subsidiary, if Borrower demonstrates to Collateral Agent's reasonable satisfaction that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code; and (iii) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral."

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Debtor has agreed not to encumber any of its Intellectual Property except as otherwise permitted by the Loan Agreement.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of California as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).

Subsidiaries of Poseida Therapeutics, Inc.:

<u>NAME</u>	<u>JURISDICTION OF INCORPORATION</u>
Vindico NanoBioTechnology, LLC	Delaware

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-240048; No. 333-256899; No. 333-262869) and Form S-3 (No. 333-258804) of Poseida Therapeutics, Inc. of our report dated March 10, 2022 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP  
San Diego, California  
March 10, 2022

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark J. Gergen, J.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Poseida Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

By: \_\_\_\_\_  
/s/ Mark J. Gergen  
Mark J. Gergen, J.D.  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Johanna M. Mylet, C.P.A., certify that:

1. I have reviewed this Annual Report on Form 10-K of Poseida Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

By: \_\_\_\_\_ /s/ Johanna M. Mylet

Johanna M. Mylet, C.P.A.

Chief Financial Officer

*(Principal Financial and Accounting Officer)*

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Poseida Therapeutics, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify to the best of my knowledge, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2022

By: \_\_\_\_\_  
/s/ Mark J. Gergen  
Mark J. Gergen, J.D.  
Chief Executive Officer  
(Principal Executive Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Poseida Therapeutics, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify to the best of my knowledge, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2022

By: \_\_\_\_\_  
/s/ Johanna M. Mylet  
Johanna M. Mylet, C.P.A.  
Chief Financial Officer  
*(Principal Financial and Accounting Officer)*

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.