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 001-36783

Bellicum Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-1450200**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

3730 Kirby Drive, Suite 1200, Houston, TX	**77098**
(Address of principal executive offices)	**(Zip code)**

(281) 454-3424
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**BLCM**	**The Nasdaq Capital 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 Section 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based upon the last sale price of the common stock as reported on The Nasdaq Capital Market as of June 30, 2021 was $26,796,617. Shares of the Registrant's common stock held by each executive officer, director and stockholder that the registrant concluded were affiliates of the registrant have been excluded from such calculation . This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 21, 2022, there were 8,552,207 shares of the Registrant's common stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to its 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days following the Registrant's fiscal year ended December 31, 2021.

BELLICUM PHARMACEUTICALS, INC.
Form 10-K
For the Fiscal Year Ended December 31, 2021

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may contain “forward-looking statements.” We may, in some cases, use words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- our ability to advance Chemical Induction of Dimerization, or CID, CID-based technologies, including CaspaCIDe and GoCAR-T;
- our ability to obtain and maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise and the success of any such collaborations;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States, or U.S., and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our ability to grow our organization and increase the size of our facilities to meet our anticipated growth;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our use of cash and other resources; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the filing date of this Annual Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading “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. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should carefully read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report by these cautionary statements.

Except as required by law, we undertake no obligation to update these forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Except as otherwise specifically indicated, all information in this Annual Report on Form 10-K has been retroactively adjusted to give effect to a 1-for-10 reverse stock-split that was effective on February 5, 2020.

Summary of Risk Factors

There are a number of risks related to our business and our securities. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found in this report on Form 10-K in Item 1A entitled "Risk Factors"

- We have incurred net losses from operations in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will require significant funding to complete the development and commercialization of our product candidates. If we fail to obtain additional financing, we may have to delay, reduce or eliminate our development programs or commercialization efforts.
- Our current product candidates are in early stage clinical trials, and we may experience unfavorable results in the future.
- Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 outbreak, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- If our efforts to protect the proprietary nature of our technologies are not adequate, we may not be able to compete effectively in our market.
- We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.
- If we fail to satisfy applicable listing standards, our common stock may be delisted from the Nasdaq Capital Market.
- Our principal stockholders own a significant percentage of our stock and can exert significant control over matters subject to stockholder approval.

ITEM 1. Business

Overview

We are a clinical stage biopharmaceutical company focused on discovering and developing novel, controllable cellular immunotherapies for the treatment of various forms of cancer. We are advancing CAR-T cell therapies, which are an innovative approach in which a patient's or donor's T cells are genetically modified to carry chimeric antigen receptors, or CARs. We are using our proprietary Chemical Induction of Dimerization, or CID, technology platform to engineer our product candidates with switch technologies that are designed to control components of the immune system in real time. By incorporating our CID platform, our product candidates may offer better efficacy and safety outcomes than are seen with current cellular immunotherapies.

Cell behavior is controlled by cascades of specialized signaling proteins. CID consists of molecular switches, modified forms of these signaling proteins, which are triggered inside the patient by infusion of a small molecule, instead of by natural upstream signals. We genetically introduce these molecular switches into immune cells and deliver the cells to the patient in the manner of conventional cellular immunotherapy. We have developed two such switches: an "activation switch," designed to stimulate activation, proliferation and persistence of the CAR-T cells and provide other immunomodulatory benefits, and a "safety switch," designed to initiate programmed cell death, or apoptosis, of the CAR-T cells. Each of our product candidates incorporates one or both switches, for enhanced, real-time control of efficacy and safety:

- The inducible MyD88/CD40 (iMC) activation switch that is incorporated into our GoCAR-T product candidates is designed to enhance CAR-T therapies by augmenting multiple mechanisms of action, including: 1) boosting effector cell proliferation; 2) enhancing functional persistence by resisting exhaustion and inhibitory signals found in the tumor microenvironment; and 3) stimulating the cancer patient's own immune system to intensify tumor killing. Unlike other CAR-T therapies that can behave unpredictably due to their autonomous activity, GoCAR-T antitumor effects are controlled through scheduled administration of rimiducid. In the event of severe side effects, GoCAR-T activity can be attenuated by extending the interval between rimiducid doses or suspending further rimiducid administration.

- Our CaspaCIDe™ safety switch (also known as inducible Caspase-9, or iC9) is designed to be inactive unless the patient experiences a serious side effect (e.g., CRS, neurologic toxicities or off-tumor / on-target toxicities). In that event, rimiducid or temsirolimus (depending on the design of the product candidate) is administered to induce Caspase-9 and eliminate the cells, with the goal of attenuating the therapy and resolving the serious side effect.

- Some of our product candidates are "dual-switch" GoCAR-Ts that are designed to provide a user-controlled system for managing proliferation, persistence and safety of tumor antigen-specific CAR-T cells by incorporating both our iMC and CaspaCIDe switches.

By incorporating our novel switch technologies, we are developing product candidates with the potential to elicit positive clinical outcomes and ultimately change the treatment paradigm in various areas of cellular immunotherapy. Our most advanced programs are described below.

- **BPX-601** is an autologous GoCAR-T product candidate containing our proprietary iMC activation switch, designed to treat solid tumors expressing prostate stem cell antigen, or PSCA. We believe iMC enhances T cell proliferation and persistence, enhances host immune activity, and modulates the tumor microenvironment to improve the potential to treat solid tumors compared to traditional CAR-T therapies. A Phase 1/2 clinical trial, called BP-012, in patients with metastatic castration-resistant prostate cancer and metastatic pancreatic cancer expressing PSCA is ongoing.

- **BPX-603** is an autologous dual-switch GoCAR-T product candidate containing both the iMC activation and CaspaCIDe safety switches. BPX-603 is our first dual-switch GoCAR-T product candidate and is designed to target solid tumors that express the human epidermal growth factor receptor 2 antigen, or HER2. A Phase 1/2 clinical trial, called BPX603-201A, in patients with metastatic HER2+ solid tumors is ongoing.

We have developed efficient and scalable processes to manufacture genetically modified T cells of high quality, which are currently being used to generate products for our clinical trials. We are leveraging this know how in combination with our proprietary cellular control technologies, resources, capabilities and expertise for the manufacture of CAR-T product candidates to create and develop first and best-in-class product candidates.

Cellular Immunotherapy

Cellular immunotherapy harnesses immune cells to attack and eliminate harmful diseased cells in the body. The immune system is the body's defense network. It consists of a number of cells (e.g., leukocytes) and organs that, working together, recognize and respond to threats in the form of pathogens-modified or transformed cells. T cells are a type of white blood cell that recognize pathogens and can target and eliminate them upon full activation through the addition of appropriate co-stimulatory signals.

CAR-T approaches entail collecting a patient's or donor's T cells, genetically modifying them ex vivo, or outside of the body, to incorporate specific receptors which target cancer cells and then infusing the modified cells into the patient. CARs are designed to target antigens on the surface of cancer cells. In early human clinical trials, CAR-T cell therapies have demonstrated an unprecedented ability to achieve complete responses in some hematological cancers, even in patients who have suffered multiple relapses.

While high objective response rates have been reported in some hematological malignancies, CAR-T therapy has shown limited clinical efficacy in solid tumors. This is likely due to poor proliferation and persistence of these cells and to immune suppressive factors found in the tumor microenvironment. In addition, patients treated with CAR-T cell therapies can have serious and sometimes fatal toxicities, which can be caused by high levels of activation of the CAR-T therapy, which can lead to severe cytokine release syndrome, or CRS, and neurologic toxicities. Furthermore, CAR-T therapies have the potential to attack healthy tissues (i.e., "on-target/off-tumor" toxicities) which can also result in death.

Our Proprietary CID Technology Platform

Our proprietary CID technology platform is designed to address the challenges of current cellular immunotherapies. Cellular activities and functions, such as growth, activation, proliferation and cell death, are controlled by signaling cascades following aggregation of specific proteins. Our CID platform consists of molecular switches, modified forms of these signaling proteins, which are triggered inside the patient by infusion of a small molecule, rimiducid or temsirolimus, instead of by natural upstream signals. Our current product candidates are based on either an "activation switch", a "safety switch," or a "dual switch" which contains both activation and safety switches. After the small molecule is administered, the "safety switch" is designed to lead to apoptosis, and the "activation switch" is designed to lead to proliferation, activation and enhanced persistence of immune cells.

We incorporate the molecular switches in the appropriate immune cells through genetic manipulation and administer them to the patient. After the gene-modified immune cells are inside the patient's body, specific functions of these cells may be controlled by administration of small molecule ligands (rimiducid or temsirolimus). The CID switch proteins have been designed to specifically bind to rimiducid or temsirolimus. Once introduced, these ligands couple, or aggregate, CID switch proteins together to create a cluster that triggers the signaling cascade. Aside from its impact on CID-modified immune cells bearing switch proteins, rimiducid is bioinert and has no other known effect on the body. In dual-switch applications, temsirolimus can be used to activate a safety switch, if severe, treatment-related toxicities occur. Temsirolimus is a kinase inhibitor approved for the treatment of advanced renal cell carcinoma that has a well-characterized safety profile.

Our proprietary CID-based product candidates depend on the following signaling molecules to trigger signaling cascades, resulting in different cell activities:

a. **iMC: Signaling Molecules for Activation and Proliferation.** iMC is also known as inducible MyD88 and CD40. Myeloid differentiation primary response 88, or MyD88, is a protein that has functions in cellular responses to stimuli such as stress, cytokines and bacteria or viruses. CD40 is a co-stimulatory protein found on antigen-presenting cells, such as dendritic cells and B cells and is required for their full activation. Activation of iMC in immune cells, such as T lymphocytes, provides inducible co-stimulation, leading to enhanced cell proliferation and survival. In addition, activation of iMC causes immune cells to secrete pro-inflammatory cytokines and chemokines, and to express co-stimulatory cell surface molecules to potentially modulate the tumor microenvironment and stimulate the patient's own immune system.

   Our GoCAR-T technology incorporates our proprietary iMC activation switch that activates CAR-T cells when triggered by both rimiducid and the targeted antigen expressed on the surface of the cancer cells. Current generation CAR-T constructs consist of a CD3 domain and one or more co-stimulatory molecules that are both activated when the CAR-T binds to the cancer antigen, and therefore, function autonomously following infusion. While current generation CAR-T cells have been effective in some hematologic malignancies, this reliance on an antigen for activation of the CAR-T cell results in an unpredictable and inherently uncontrollable therapeutic effect and potential associated toxicity. Further, in solid tumor settings, current generation CAR-T cells often fail to proliferate or persist for more than a few days or weeks and have been largely ineffective. In each situation, the physician has no effective way to intervene to achieve greater consistency once the cells have been administered.

Our GoCAR-T technology is designed to change the current paradigm by placing our proprietary co-activation domain, MC, under rimiducid control. GoCAR-T cells are designed to only be fully activated when exposed to both the cancer cells expressing the target antigen and rimiducid. This separation is designed to control the degree of activation of the CAR-T cells through adjustments to the schedule of rimiducid dosing.

b. **CaspaCIDe: Signaling Molecule for Apoptosis.** CaspaCIDe is also known as inducible Caspase-9. Caspase-9 is the initiating enzyme in the apoptosis pathway. When activated, the dimerization of CaspaCIDe leads to rapid apoptosis of gene-modified T cells. Because CaspaCIDe is designed to be permanently integrated into our cellular therapies, the safety switch has the potential to be available for use long after the initial therapy is delivered. Moreover, preclinical animal studies demonstrate the ability to modulate the elimination of cells containing CaspaCIDe by different rimiducid doses and schedules (i.e., titrated elimination).

CaspaCIDe has been incorporated into several clinical programs. At the American Society of Hematology Annual Meeting in 2018, we presented data on the administration of rimiducid to trigger CaspaCIDe in 24 patients experiencing graft versus host disease (GvHD) refractory to standard treatments after receiving rivo-cel following stem cell transplantation. The best overall GvHD clinical response after rimiducid administration was 70%, with a median time to response of one day.

On March 4, 2021, we announced the first reported case of the use of CaspaCIDe to mitigate a severe CAR T-mediated adverse event refractory to standard of care treatment. The report in *Blood*, a journal published by the American Society of Hematology, detailed a case from an investigator sponsored trial at the University of North Carolina Lineberger Comprehensive Cancer Center of a CD19 CAR-T containing CaspaCIDe. A patient in the study experienced grade 3-4 immune effector cell-associated neurotoxicity syndrome (ICANS) for 72 hours despite standard care. Within 12 hours of rimiducid administration, ICANS grade improved from 3 to 1 and was fully resolved after four days.

In addition to being incorporated in some of our product candidates, CaspaCIDe has been licensed to several entities for use in their CAR-T and CAR-NK programs. Under these agreements, Bellicum grants license to the use of CaspaCIDe and access to supply of rimiducid in exchange for a proportion of the economics of these programs as they advance and generate revenue for the licensee, including a single-digit-percent royalty on global net sales should they be approved by regulators. Currently, these agreements cover seven CAR-T or CAR-NK programs, with the option to expand to additional programs over time.

Our Active Product Candidates

BPX-601: GoCAR-T for PSCA+ Solid Tumors

We are developing BPX-601, an autologous GoCAR-T product candidate containing our proprietary iMC activation switch, designed to treat solid tumors expressing prostate stem cell antigen, or PSCA. PSCA is an antigen expressed in several solid tumor indications, including prostate and pancreatic cancer. Pre-clinical data show iMC enhances T cell proliferation and persistence, enhances host immune activity, and modulates the tumor microenvironment to improve the potential to treat solid tumors compared to traditional CAR-T therapies. A Phase 1/2 clinical trial, called BP-012, in patients with metastatic castration-resistance prostate, or mCRPC, and pancreatic cancer expressing PSCA is ongoing. In December, 2021, we announced that one of the first three mCPRC patients treated in the study achieved a confirmed Partial Response by RECIST v1.1 criteria. Additionally, no dose-limiting toxicities were observed.

BPX-603: Dual-Switch GoCAR-T for HER2+ Solid Tumors

We are developing BPX-603, which is our first controllable dual-switch autologous GoCAR-T product candidate and incorporates both the iMC activation switch and the CaspaCIDe safety switch. BPX-603 is designed to target solid tumors that express the human epidermal growth factor receptor 2 antigen, or HER2. HER2 is a validated antigen for cancer therapies, and academic HER2 CAR-T cell clinical studies have shown evidence of anti-tumor activity. These academic HER2 CAR-T approaches targeting HER2 have been limited by modest clinical efficacy and off-tumor/on-target toxicity. We believe that our dual-switch GoCAR-T technology may be uniquely suited to improve upon these earlier efforts, by driving greater efficacy through iMC activation while enabling clinicians to manage any treatment-emergent toxicities with CaspaCIDe. A Phase 1/2 clinical trial, called BPX603-201A, in patients with metastatic HER2+ solid tumors is ongoing.

Manufacturing, Processing and Delivering to Patients

We have developed efficient and scalable processes to manufacture genetically modified T cells of high quality. We are leveraging the processes we have developed for BPX-601 in combination with our proprietary cellular control technologies,

resources, capabilities and expertise for the manufacture of our product candidates to create and develop first and best-in-class product candidates.

Our product candidates require a combination of three critical components: (1) viral vectors with DNA content encoded for our proprietary switch proteins and co-stimulatory and other accessory molecules, (2) patient-derived T cells that are genetically modified by our viral vectors, and (3) the small molecules rimiducid and/or temsirolimus, which activate the switch proteins. Each of these components requires a separate supply chain and shares the same regulatory requirements applicable for biological or chemical materials suitable for human use. Details on each of these components are described below:

a. ***Viral Vectors.*** We use gamma retrovirus to transduce our product candidates. We believe that gamma retrovirus is optimal for cell transduction given that it is an integrating vector that induces long-term gene expression, exhibits high transduction efficiency, has sufficient capacity for DNA content, and has been extensively and safely used in clinical trials.

b. ***Genetically Modified Cells.*** We have designed and refined a proprietary process for cell engineering that has been improved from lab-based open procedures used in academic and research settings to a functionally closed system that is more appropriate for large-scale clinical trials and commercialization. Our systems are designed to be compliant with current guidelines and regulations for cell-based manufacturing in the U.S. and Europe and have been successfully implemented by our third-party manufacturers.

c. ***Small Molecules.*** Rimiducid is a synthetic small molecule that has been rationally designed to trigger the proprietary switch proteins in our CID platform. We have separate third-party manufacturers for the active pharmaceutical ingredient, or API, and the finished drug product. Manufacturers of both the API and finished drug product are licensed to manufacture a variety of marketed drugs worldwide and have been selected based on their ability to provide supplies for our clinical trials and future commercialization. In our dual-switch constructs, the small molecule temsirolimus can be used to trigger one of the two switches. Temsirolimus is an approved and commercially available product manufactured and distributed by Pfizer Inc. under the trade name TORISEL.

We are focused on continuously refining our overall cell therapy supply chain, manufacturing, processing and delivery to patients to be more efficient. Our current process cycles for our autologous product candidates, from collection of white blood cells to infusion of the final product, can be completed in as little as four weeks and are customized to be complementary to the treatment procedure of interest in order to prevent delays or complications.

Intellectual Property

We seek to protect proprietary technology, inventions, and improvements that are commercially important to our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also seek to rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity and patent term extensions where available as well as contractual agreements with our academic and commercial partners.

A strategic focus for us has been to identify and license key patents and patent applications that serve to enhance our intellectual property and technology position. Our intellectual property estate includes: (1) claims directed to core CID technologies and components used in our products; (2) claims directed to methods of treatment for therapeutic indications; (3) claims directed to specific products; and (4) claims directed to innovative methods for generating new constructs for genetically engineering T cells. We believe our patent estate, together with our efforts to develop and patent next generation technologies, provides us with a substantial intellectual property position.

As of December 31, 2021, to our knowledge, our patent estate, on a worldwide basis, includes 187 issued patents, 26 of which are in the U.S., and 67 pending patent applications, 16 of which are in the U.S., which we own or for which we have an exclusive, either in its entirety or within our field of use, commercial license. The provisional and pending patent applications and issued patents include composition of matter and method of use claims.

- We have internally developed technology disclosed in seven pending utility patent applications in the U.S., one European granted patent validated in eight countries, and 25 pending foreign patent applications that relate to our GoCAR-T technology. If U.S. patents issue from the U.S. applications, the estimated expiration date of the last to expire patent is in 2039. If patents are issued in foreign jurisdictions, the anticipated expiration dates will be in 2039.
- Pursuant to our licenses from Baylor and Ariad, we have exclusive commercial rights to 12 issued U.S. patents expiring in 2024 or later, four pending U.S. utility patent applications, two European granted patents (the first

validated in three countries, the second validated in ten countries), four issued foreign patents expiring in 2024 or later and two pending patent applications in foreign jurisdictions that relate to our GoCAR-T, rivo-cel and certain of our other technologies. If U.S. patents issue from the currently pending U.S. patent applications, the estimated expiration date of the last to expire patent is 2031. If patents from the currently pending patent applications are issued in foreign jurisdictions, the estimated expiration dates range from 2024 to 2029.

- Pursuant to our license agreement with Agensys we have exclusive commercial rights for technology to target certain cancer-specific antigens.

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, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or the USPTO, in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. The term of a patent that covers an FDA-approved drug or biologic may also be eligible for a patent term restoration of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term restoration is calculated based on the length of time the drug or biologic is under regulatory review. A patent term restoration under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug or biologic may be restored. Moreover, a patent can only be restored once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. When possible, depending upon the length of clinical trials and other factors involved in the filing of a Biologics License Application, or BLA, we expect to apply for patent term extensions for patents covering our product candidates and their methods of use.

We may rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any 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 know-how and inventions.

Our Collaboration and License Agreements

Co-Development and Co-Commercialization Agreement - Adaptimmune

In December 2016, we and Adaptimmune Therapeutics plc, or Adaptimmune, entered into a Co-Development and Co-Commercialization Agreement, or the Adaptimmune Agreement, in order to facilitate a staged collaboration to evaluate, develop and commercialize next generation T cell therapies.

Under the Adaptimmune Agreement, the parties agreed to evaluate our GoTCR technology, iMC co-stimulation, with Adaptimmune's affinity-optimized SPEAR® T cells for the potential to create enhanced TCR product candidates. Depending on results of the preclinical proof-of-concept phase, the agreement may progress to a two-target co-development and co-commercialization phase. To the extent necessary, and in furtherance of the parties' proof-of-concept and co-development efforts, the parties granted each other a royalty-free, non-transferable, non-exclusive license covering their respective technologies for purposes of facilitating such proof-of-concept and co-development efforts. In addition, as to covered therapies developed under the Adaptimmune Agreement, the parties granted each other a reciprocal exclusive license for the commercialization of such therapies.

With respect to any joint commercialization of a covered therapy, the parties agreed to negotiate in good faith the commercially reasonable terms of a co-commercialization agreement. The parties also agreed that any such agreement shall provide for, among other things, equal sharing of the costs of any such joint commercialization and the calculation of profit shares as set forth in the Adaptimmune Agreement.

The Adaptimmune Agreement will expire on a country-by-country basis once the parties cease commercialization of the T cell therapies covered by the Adaptimmune Agreement, unless earlier terminated by either party for material breach, non-performance or cessation of development, bankruptcy/insolvency, or failure to progress to co-development phase.

License Agreement - Agensys

In December 2015, we and Agensys, Inc., or Agensys, entered into a license agreement, or the Agensys Agreement, pursuant to which (i) Agensys granted us, within the field of cell and gene therapy of diseases in humans, an exclusive, worldwide license and sublicense to its patent rights directed to PSCA and related antibodies, and (ii) we granted Agensys a non-exclusive, fully paid license to our patents directed to inventions that were made by us in the course of developing our licensed products, solely for use with Agensys therapeutic products containing a soluble antibody that binds to PSCA or, to the extent not based upon our other proprietary technology, to non-therapeutic applications of antibodies not used within the field.

As consideration for the rights granted to us under the Agensys Agreement, we agreed to pay to Agensys a non-refundable upfront fee of $3.0 million. We are also required to make aggregate milestone payments to Agensys of up to (i) $5.0 million upon the first achievement of certain specified clinical milestones for its licensed products, (ii) $50.0 million upon the achievement of certain specified clinical milestones for each licensed product, and (iii) $75.0 million upon the achievement of certain sales milestones for each licensed product. The Agensys Agreement additionally provides that we will pay to Agensys a royalty percentage that ranges from the mid to high single digits based on the level of annual net sales of licensed products by us, our affiliates or permitted sublicensees. The royalty payments are subject to reduction under specified circumstances.

Under the Agensys Agreement, Agensys also was granted the option to obtain an exclusive license, on a product-by-product basis, from us to commercialize in Japan each licensed product developed under the Agensys Agreement that has completed a phase 2 clinical trial. As to each such licensed product, if Agensys or its affiliate, Astellas Pharma, Inc., exercises the option, the Agensys Agreement provides that we will be paid an option exercise fee of $5.0 million. In addition, the Agensys Agreement provides that we will be paid a royalty that ranges from the mid to high single digits based on the level of annual net sales in Japan of each such licensed product. If the option is exercised, the aggregate milestone payments payable by us to Agensys, described above with respect to each licensed product, would be reduced by up to an aggregate of $65.0 million upon the achievement of certain specified clinical and sales milestones.

The Agensys Agreement will terminate upon the expiration of the last royalty term for the products covered by the Agensys Agreement, which is the earlier of (i) the date of expiration or abandonment of the last valid claim within the licensed patent rights covering any licensed products under the Agensys Agreement, (ii) the expiration of regulatory exclusivity as to a licensed product, and (iii) 10 years after the first commercial sale of a licensed product. Either party may terminate the Agensys Agreement upon a material breach by the other party that remains uncured following 60 days after the date of written notice of such breach (or 30 days if such material breach is related to failure to make payment of amounts due under the Agensys Agreement) or upon certain insolvency events. In addition, Agensys may terminate the Agensys Agreement immediately upon written notice to us if we or any of our affiliates or permitted sublicensees commence an interference proceeding or challenge the validity or enforceability of any of Agensys' patent rights.

License Agreement - BioVec

In June 2015, we and BioVec Pharma, Inc., or BioVec, entered into a license agreement, or the BioVec Agreement, pursuant to which BioVec agreed to supply us with certain proprietary cell lines and granted us a non-exclusive, worldwide license to certain of its patent rights and related know-how related to such proprietary cell lines.

As consideration for the products supplied and rights granted to us under the BioVec Agreement, we agreed to pay to BioVec an upfront fee of $100,000 within ten business days of the effective date of the BioVec Agreement and a fee of $300,000 within ten business days of its receipt of the first release of GMP lot of the products licensed under the BioVec Agreement. In addition, we agreed to pay to BioVec an annual fee of $150,000, commencing 30 days following the first filing of an IND, or its foreign equivalent, for a product covered by the license; with such annual fees being creditable against any royalties payable by us to BioVec under the BioVec Agreement. We also are required to make a $250,000 milestone payment to BioVec for each of the first three licensed products to enter into a clinical phase trial and one-time milestone payments of $2.0 million upon receipt of a registration granted by the FDA or EMA on each of our first three licensed products. The BioVec Agreement additionally provides that we will pay to BioVec a royalty in the low single digits on net sales of products covered by the BioVec Agreement. We may also grant sub licenses under the licensed patent rights and know-how to third parties for limited purposes related to the use, sale and other exploitation of the products licensed under the BioVec Agreement. The BioVec Agreement will continue until terminated. The BioVec Agreement may be terminated by us, in our sole discretion, at any time upon 90 days written notice to BioVec. Either party may terminate the BioVec Agreement in the event of a breach by the other party of any material provision of the BioVec Agreement that remains uncured on the date that is 60 days after written notice of such failure or upon certain insolvency events that remain uncured following the date that is 30 days after the date of written notice to a party regarding such insolvency event.

License Agreements - Baylor College of Medicine

2008 Baylor License Agreement

Pursuant to an Exclusive License Agreement with Baylor College of Medicine, or Baylor, dated March 20, 2008, or the 2008 Baylor license agreement, we obtained an exclusive, worldwide and fully paid up license to certain intellectual property, including intellectual property related to methods for activating antigen presenting cells and to genetic constructs coding for membrane bound inducible cytoplasmic CD40.

As consideration for the 2008 Baylor license agreement, we issued to Baylor 23,529 shares of our common stock and assumed responsibility for all legal fees and expenses, filing or maintenance fees, assessments and all other costs and expenses related to prosecuting, obtaining and maintaining patent protection on the patents subject to the 2008 Baylor license agreement.

The 2008 Baylor license agreement is subject to certain restrictions and is nonexclusive with respect to (1) the making or use of the licensed intellectual property for use in non-commercial research, patient care, teaching, and other educational purposes; (2) any non-exclusive license covering the licensed intellectual property that Baylor grants to other academic or research institutions for noncommercial research purposes; (3) any non-exclusive licenses that Baylor is required to grant to the U.S. or foreign state pursuant to an existing or future treaty with the U.S.; and (4) a non-exclusive license granted to ARIAD Pharmaceuticals, Inc. or ARIAD under the terms of a materials transfer agreement between Baylor and ARIAD.

Baylor may terminate or modify the 2008 Baylor license agreement in the event of a material breach by us that remains uncured following the date that is 90 days after written notice of such breach or upon certain insolvency events that remain uncured following the date that is 30 days following written notice of such insolvency event. We may terminate the 2008 Baylor license agreement, or any portion thereof, at our sole discretion at any time upon 30 days' written notice to Baylor. Upon termination of the 2008 Baylor license agreement, all rights to the intellectual property immediately revert to Baylor.

2010 Baylor License Agreement

Pursuant to an Exclusive License Agreement with Baylor, dated June 27, 2010, or the 2010 Baylor license agreement, we obtained an exclusive, worldwide license to certain intellectual property, including intellectual property related to methods for treating prostate cancer, methods of administering T cells to a patient, and methods of activating antigen presenting cells with constructs comprising MyD88 and CD40.

Pursuant to the terms of the 2010 Baylor license agreement we are required to pay a low annual maintenance fee on each anniversary of the agreement date.

The terms of the 2010 Baylor license agreement also require us to make royalty payments of less than one percent, subject to certain annual minimums, on net sales of products covered by the license. In addition, to the extent we enter into a sublicensing agreement relating to a licensed product, we are required to pay Baylor a percentage in the mid-single digits on all non-royalty income received from sublicensing revenue. Bellicum is required to make milestone payments, of up to $735,000 in aggregate, upon successful completion of clinical and regulatory milestones regarding the first two products covered by this license.

The 2010 Baylor license agreement will expire upon expiration of the last patent contained in the licensed patent rights, on a country-by-country basis, upon which we will have a perpetual, paid-in-full license in such country. Baylor may terminate or modify the 2010 Baylor license agreement in the event of a material breach by us that remains uncured following the date that is 90 days after written notice of such breach or upon certain insolvency events that remain uncured following the date that is 30 days following written notice of such insolvency event. We may terminate the 2010 Baylor license agreement, or any portion thereof, at our sole discretion at any time upon 60 days' written notice to Baylor. Upon termination of the 2010 Baylor license agreement for any reason prior to expiration, we must assign to Baylor each authorized sublicense agreement that is currently in effect on the date of termination.

2014 Baylor License Agreement

Pursuant to an Exclusive License Agreement with Baylor, effective November 1, 2014, or the 2014 Baylor license agreement, we obtained an exclusive, worldwide license to certain intellectual property, including intellectual property related to methods for inducing selective apoptosis.

Pursuant to the terms of the 2014 Baylor license agreement we are required to pay Baylor a low annual maintenance fee on each anniversary of the agreement date. The terms of the 2014 Baylor license agreement also require us to make royalty payments in the low single digits, subject to certain annual minimums, on net sales of products covered by the license. To the extent we enter into a sublicensing agreement relating to a licensed product, Bellicum is also required to pay Baylor a percentage in the low

double-digits on all non-royalty income received from sublicensing revenue. We are required to make milestone payments, of up to $275,000 in aggregate, upon successful completion of clinical and regulatory milestones regarding the first product covered by this license. The 2014 Baylor license agreement will expire upon expiration of the last patent contained in the licensed patent rights, on a country-by-country basis, upon which we will have a perpetual, paid-in-full license in each such country.

Baylor may terminate or modify the 2014 Baylor license agreement in the event of a material breach by us that remains uncured following the date that is 90 days after written notice of such breach or upon certain insolvency events that remain uncured following the date that is 30 days following written notice of such insolvency event. We may terminate the 2014 Baylor license agreement, or any portion thereof, at our sole discretion at any time upon 60 days' written notice to Baylor.

2016 Baylor License Agreements

In March 2016, we and Baylor entered into two additional license agreements pursuant to which we obtained exclusive rights to technologies and patent rights owned by Baylor. We could incur additional payments upon the achievement of certain milestone events as set forth in the agreements. If we are successful in developing any of the licensed technologies under either agreement, resulting sales would be subject to a royalty payment in the low single digits.

Grant Agreements

Grant Agreements with Cancer Prevention and Research Institute of Texas

In July 2011, we entered into a Cancer Research Grant Contract, or the First Grant Contract, with the Cancer Prevention and Research Institute of Texas, or CPRIT, under which CPRIT awarded a grant not to exceed approximately $5.7 million to be used for the execution of defined clinical development of rivo-cel. To date, we have received approximately $4.9 million under the grant. The First Grant Contract terminated on June 30, 2014, but obligations exist as to licensing, royalty payments, and indemnification provisions.

In November 2016, we announced that the Company received notice of a product development award totaling approximately $16.9 million from CPRIT. The CPRIT award was expected to fund a portion of a three-year global clinical program comprising clinical trials for adult and pediatric patients with high-risk and intermediate-risk AML, and potentially other hematologic cancers. The proposed studies are designed to evaluate the benefit of rivo-cel and rimiducid in the context of in vivo and ex vivo T cell depleted haploidentical HSCT. The CPRIT oversight committee met in February 2017 and agreed to move forward with the proposed terms of the grant agreement, and a second grant, or the Second Grant Contract was entered into in August 2017. Additionally, the First Grant Contract was amended in order to align revenue sharing terms, discussed below, with the Second Grant Contract. We initiated a pivotal randomized Phase 2/3 clinical trial (THRIVE) supported in part by the CPRIT funding.

In January 2020, we terminated the Second Grant Contract based on our decision to cease enrollment of the THRIVE trial. A total of approximately $3.3 million in grant funds was received and used for the project.

No additional funds will be disbursed under this grant, but the revenue share and other post-grant obligations described below survive the termination.

Pursuant to the terms of each of the Grant Contracts, we grant to CPRIT a non-exclusive, irrevocable, royalty-free, perpetual, worldwide license to any technology and intellectual property resulting from the grant-funded activities and any other intellectual property that is owned by us and necessary for the exploitation of the technology and intellectual property resulting from the grant-funded activities, or the Project Results, for and on behalf of CPRIT and other governmental entities and agencies of the State of Texas and private or independent institutions of higher education located in Texas for education, research and other non-commercial purposes only. The terms of each of the Grant Contracts require that we pay tiered royalties in the low- to mid-single digit percentages on revenues from sales and licenses of products or services that are based upon, utilize, are developed from or materially incorporate Project Results. Such royalties reduce to less than one percent after a mid-single-digit multiple of the grant funds have been repaid to CPRIT in royalties. Such royalties are payable for so long as we have marketing exclusivity or patents covering the applicable product or service (or twelve years from first commercial sale of such product or service in certain countries if there is no such exclusivity or patent protection).

If we abandon patent applications or patents covering Project Results in certain major market countries, CPRIT can, at its own cost, take over the prosecution and maintenance of such patents and is granted a non-exclusive, irrevocable, royalty-free, perpetual license with right to sublicense in such country to the applicable Project Results. We are required to use diligent and commercially reasonable efforts to commercialize at least one commercial product or service or otherwise bring to practical application the Project Results. If CPRIT notifies us of our failure with respect to the foregoing, and such failure is not owing to

material safety concerns, then, at CPRIT's option, the applicable Project Results would be transferred to CPRIT and CPRIT would be granted a non-exclusive license to any other intellectual property that is owned by us and necessary for the exploitation of the Project Results, and CPRIT, at its own cost, can commercialize products or services that are based upon, utilize, are developed from or materially incorporate Project Results. CPRIT's option is subject to our ability to cure any failures identified by CPRIT within 60 days and a requirement to negotiate in good faith with us with respect to an alternative commercialization strategy for a period of 180 days

Competition

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary CID platform, differentiated product candidates and scientific expertise in the field of cellular immunotherapy provide us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

Cell based treatments for cancer, such as CAR-T therapies, have recently been an area of significant research and development by academic institutions and biopharmaceutical companies. Our product candidates may compete with product candidates from a number of companies that are currently focused on this therapeutic modality, including 2seventy bio, Inc., Adaptimmune, Alaunos Therapeutics, Inc., Allogene Therapeutics, Inc., Amgen Inc., Atara Biotherapeutics, Inc., Athenex, Inc., Autolus Therapeutics plc, BioNTech Europe GmbH, Bristol-Meyer Squibb Co., Cellectis SA, Celyad S.A., CRISPR Therapeutics, Fate Therapeutics Inc., GlaxoSmithKline plc, Gilead Sciences, Inc., Immatics N.V., ImmunityBio, Inc., Iovance Biotherapeutics, Inc., Janssen Pharmaceutical, Legend Biotech, Lyell Immunopharma, Inc., Medigene AG, Mustang Bio, Inc., Novartis AG, Obsidian Therapeutics, Poseida Therapeutics, Precigen Inc., Precision Biosciences, Inc., Sana Biotechnology, Sorrento Therapeutics, Inc., and Takeda Pharmaceutical Co.

In addition to other cell based treatments, our product candidates may compete in their solid tumor indications with novel therapeutics of other modalities, including small molecules, monoclonal antibodies, bi-specific antibodies, antibody-drug conjugates, and targeted radionuclides.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance. Our competitors' treatments may be more effective, or more effectively marketed and sold, than any treatment we may commercialize and may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our treatments.

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

We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payers. For example, if a third party is able to obtain a stand-alone new drug application for rimiducid, then potential generic manufacturers may be able to file abbreviated new drug applications for that product.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that our therapeutic products, if approved, will be priced at a significant premium over competitive generic products and our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products.

Government Regulation and Product Approval

As a biopharmaceutical company that operates in the U.S., we are subject to extensive regulation. Our cell products will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered and licensed facilities in compliance with the current good manufacturing practice, or cGMP, for biologics.

The FDA regulates human cells, tissues, and cellular and tissue-based products, or HCT/Ps, under a two-tiered framework, based on risk categorization. Higher-risk HCT/Ps are regulated as biologics. For example, such products must complete extensive clinical trials, which must be conducted pursuant to an effective IND. The FDA must review and approve a Biologics License Application, or BLA before a new biologic may be marketed.

The FDA considers our investigational products to be "combination products" because our products involve a biologic, the engineered cells, that is intended to be used with a small molecule chemical drug, rimiducid. In general, biologics such as our engineered cells are regulated through the FDA's Center for Biologics Evaluation and Research, or CBER, while synthetic drugs are regulated through the FDA's Center for Drug Evaluation and Research. When the FDA encounters a combination product such as our products, the agency determines which of the two centers will have primary responsibility for regulating the product by determining the primary mode of action for the product. The cellular component of our combination contributes the primary mode of action and, as a result, the FDA will regulate our investigational products as biologics, through CBER.

Government authorities in the U.S., at the federal, state and local levels, and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the U.S. and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects.

U.S. Product Development Process

In the U.S., the FDA regulates new drugs and biological products under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process required by the FDA before a biological product may be marketed in the U.S. generally involves the following:

a. completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

b. submission to the FDA of an IND, which must become effective before human clinical trials may begin;

c. performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

d. submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

e. satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of HCT/Ps;

f. potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

g. FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product

chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor must resolve FDA's outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

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

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

a. *Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

b. *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

c. *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

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

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the progress of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

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

Federal law requires that we register all of our clinical trials on a publicly accessible website and provide results information for most of our clinical trials, other than Phase 1 clinical trials.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of certain data or full or partial waivers.

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

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

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require HCT/P establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To maintain compliance with CGMPs, GTPs, and GCPs, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical

trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS or other risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, the PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s). Sponsors in satisfaction of this obligation may receive an additional six months of marketing exclusivity for all dosage forms and all indications with the same active moiety as the drug studied.

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 generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. 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 shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of PDUFA fees, enhanced access to FDA staff, and potential waiver of the PREA requirements discussed above.

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 product 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 user fee.

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

Expedited Development and Review Programs

The FDA has a Fast Track program that 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, or if the drug has been designated as a qualified infectious disease product. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Under Fast Track, 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. Even if Fast Track designation is granted, it may be rescinded if the product no longer meets the qualifying criteria.

Any product, submitted to the FDA for approval, including a product with a Fast Track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A

product is eligible for priority review if it treats a serious condition and, if approved, would provide a significant improvement in safety and efficacy. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. 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 treats a serious condition, provides a meaningful advantage over available therapies, and demonstrates 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 approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform appropriate post-marketing clinical studies to verify and describe the predicted 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. The FDCA also provides expedited procedures for FDA withdrawal of approval of a product approved through accelerated approval. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Breakthrough Therapy Designation is intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation requires preliminary clinical evidence that may demonstrate substantial improvement on a clinically significant endpoint over available therapies. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance, organizational commitment, and other potential actions to expedite review. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same product if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will expedite the development and review of such product. Even if a Breakthrough Therapy Designation is granted, it may be rescinded if the product no longer meets the qualifying criteria.

Other U.S. Health Care Laws and Compliance Requirements

In the U.S., 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 and 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, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, the sunshine provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, and similar state laws, each as amended.

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 either the referral of an individual, or for the purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal health care programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biologic manufacturers on one hand and prescribers, purchasers, and formulary managers 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 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.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act 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. The Anti-Kickback Statute may be violated if only one purpose of the remuneration is to induce referrals. In addition, the Affordable Care Act 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 civil False Claims Act.

The civil monetary penalties law imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws, including but not limited to the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government. Pharmaceutical and other health care 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, that is, off-label, and thus non-reimbursable, uses.

HIPAA created additional new federal criminal statutes that prohibit 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 health care benefit program, including private third-party payors 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 health care benefits, items or services.

Also, many states have similar 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.

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, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity, and their covered subcontractors. 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 the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act, 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, to report annually 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 healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and require that certain manufacturers and group purchasing organizations report annually certain ownership and investment interests held by physicians and their immediate family members.

We will also be required to begin satisfying the product tracing, verification, and reporting requirements set out in the Drug Supply Chain Security Act.

In order to distribute products commercially, we must also 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.

Several states have enacted legislation requiring pharmaceutical and biotechnology companies to, among other things, 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 health care 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.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including significant administrative, civil and criminal penalties, damages, fines, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, exclusion from participation in government health care programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm and the curtailment or restructuring of our operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and markets in other countries, 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 U.S., third-party payors include federal and state health care programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. 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. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, 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 very 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 adequate coverage and reimbursement. In addition, emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on health care pricing. 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.

Health Reform

In the United States and some foreign jurisdictions, there have been, and we anticipate there will continue to be, several legislative and regulatory changes and proposed healthcare reform measures with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, the PPACA has been subject to executive branch, judicial and Congressional challenges. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. 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 PPACA 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 PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. Moreover, payment methodologies may also be subject to changes in healthcare legislation and regulatory initiatives. In addition, there has been increasing legislative and executive branch interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, Presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, 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 as well as potential administrative actions HHS can take 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. It is unclear whether these or similar policy initiatives will be implemented in the future. 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. It is also 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 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 U.S. to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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.

Employees

As of December 31, 2021, we had 7 employees, all of whom were full-time, 5 of whom were engaged in research and development activities and 2 of whom were engaged in general and administrative activities. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve objectives.

The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage healthy behaviors; and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the community in which we operate, and which comply with government regulations, including working from home.

Corporate Information

We were incorporated in Delaware in July 2004. Our principal executive office is located at 3730 Kirby Drive, Suite 1200, Houston, Texas and our telephone number is (281) 454-3424. Our corporate website address is www.bellicum.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The contents of our website are not incorporated into this Annual Report and our reference to the URL for our website is intended to be an inactive textual reference only.

Item 1A. Risk Factors

Our business and results of operations are subject to a number of risks and uncertainties. You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to Our Business and Industry

We have incurred net losses from operations in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical stage biopharmaceutical company, have no products approved for commercial sale and have incurred significant losses since our inception in 2004. To date, we have financed our operations primarily through equity and debt financings. For the fiscal years ended December 31, 2021 and 2020, we reported a net loss of $9.7 million and $7.7 million, respectively. As of December 31, 2021, we had an accumulated deficit of $550.5 million. We expect to continue to incur significant losses from operations for the foreseeable future, and we expect these accumulated losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

In addition, if we obtain regulatory approval of and seek to commercialize any of our product candidates, we will likely incur significant sales, marketing and manufacturing expenses and may continue to incur substantial research and development expenses for additional post-marketing approval development requirements related to such product.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require significant funding to complete the development and commercialization of our product candidates. If we fail to obtain additional financing, we may have to delay, reduce or eliminate our development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates and other research and development programs.

As of December 31, 2021, we had cash, cash equivalents and restricted cash of approximately $47.7 million. We maintain our cash and cash equivalents with high quality, accredited financial institutions. These amounts at times may exceed federally insured limits. Cash, cash equivalents and restricted cash are expected to be sufficient to fund our operating expenses and capital expenditure requirements through at least one year from the financial statement issuance date.

We will need to finance future cash needs through public or private equity offerings, debt financings, strategic partnerships and alliances or licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the pandemic. If the disruption persists and/ or deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity to fund research and development programs, including discovery research, preclinical and clinical development activities. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to significantly delay, scale back or discontinue the development or commercialization of our product candidates. We also could be required to:

- seek collaborators for one or more of our current or future product candidates on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- seek a third party to acquire us or our assets.

If we are unable to raise additional funds on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our development programs, or implement further reduction of costs for facilities and administration beyond our October 2020 restructuring. Moreover, if we do not obtain such additional funds, there could be substantial doubt about our ability

to continue as a going concern and increased risk of insolvency, which could result in a total loss of investment to our stockholders and other security holders.

The FDA and other regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Our business and future success depends, in part, on our ability to obtain regulatory authority assent to conduct human clinical trials, obtain regulatory approval to launch a product based on evidence of clinical safety and efficacy and then successfully commercialize our clinical product candidates. All of our product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, and access to sufficient commercial manufacturing capacity and significant marketing efforts before we can expect to generate any revenue from product sales.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- The FDA or comparable regulatory authority or an Institutional Review Board or comparable ethics oversight body may decline to clear the applicable Investigational New Drug Application (IND) or equivalent regulatory submission necessary to conduct human clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates have the necessary safety, purity, and potency for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- we may encounter serious and unexpected adverse events during clinical trials that render our products unsafe for use in humans;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in Europe, the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes and/or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable.

We have devoted substantially all of our financial resources and efforts to developing our proprietary CID technology platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We are in the early stages of developing our product candidates, and we have not completed development of any products. Our ability to generate revenue and achieve profitability depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of products for the foreseeable future. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing requisite clinical trials through all phases of clinical development of our current product candidates;
- seeking and obtaining marketing approvals for product candidates that successfully complete clinical trials, if any;
- launching and commercializing product candidates for which we obtain marketing approval, if any, with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- identifying and developing new product candidates;
- progressing our pre-clinical programs into human clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- developing new molecular switches based on our proprietary CID technology platform;
- maintaining, protecting, expanding and enforcing our intellectual property; and

- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with biologic product development, we are unable to predict the likelihood or timing for when we may receive regulatory approval of any of our current or future product candidates or when we will be able to achieve or maintain profitability, if ever. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain the regulatory approvals to market and sell one or more of our product candidates, we may never generate significant revenues from any commercial sales for several reasons, including because the market for our products may be smaller than we anticipate, or products may not be adopted by physicians and payors or because our products may not be as efficacious or safe as other treatment options. If we fail to successfully commercialize one or more products, we may be unable to generate sufficient revenues to sustain and grow our business and our business, prospects, financial condition and results of operations will be adversely affected. In addition, our expenses could increase beyond expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies and clinical trials in addition to those that we currently anticipate for our product candidates, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates. Further, if one or more of the product candidates that we independently develop is approved for commercial sale, we expect to incur significant costs associated with commercializing any such product candidates. Finally, even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our CID technology is novel and largely unproven.

Our proprietary CID technology platform is novel and there are no approved products or third-party product candidates in late-stage clinical trials based on this technology. Additionally, the safety and efficacy profile of rimiducid has not been subject to large scale clinical testing. If rimiducid is found to have a poor safety profile in clinical trials, or if our technology is not effective, we may be required to redesign all of our product candidates, which would require significant time and expense. In addition, our CID platform technology may not be applicable or effective in the development of additional cellular immunotherapies beyond our current programs which would adversely affect our business and prospects.

Cell therapies are novel and present significant challenges.

CAR-T and other cell therapy product candidates represent a relatively new field of cellular immunotherapy. Advancing this novel and personalized therapy creates significant challenges for us, including:

- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of cell therapies for cancer;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a consistent and reliable process, while limiting contamination risks, for engineering and manufacturing T cells ex vivo and infusing the engineered cells into the patient;
- educating medical personnel regarding the potential safety benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapy.

Our inability to successfully develop CAR-T and other cell therapies or develop processes related to the manufacture or commercialization of these therapies would adversely affect our business, results of operations and prospects.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Clinical testing is expensive, takes many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our product candidates are subject to the risks of failure inherent in biologic drug development. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing, even at statistically significant levels. We will be required to demonstrate through clinical trials that our product candidates are safe and effective for use in the target indication before we can obtain regulatory approvals for commercial sale. Companies frequently suffer significant setbacks in late-stage clinical trials, even after earlier clinical trials have shown promising results and most product candidates that commence clinical trials are never approved as products. We expect there may be greater variability in results for cellular immunotherapy products processed and administered on a patient-by-patient basis like some of our CID technology-based development and product candidates than for “off-the-shelf” products, like many drugs.

If any of our product candidates fail to demonstrate sufficient safety or efficacy, we would experience potentially significant delays in, or be required to abandon our development of the product candidate, which would have a material and adverse impact on our business, prospects, financial condition and results of operations.

Our current product candidates are in early stage clinical trials, and we may experience unfavorable results in the future.

A Phase 1/2 clinical trial is ongoing for BPX-601 for the treatment of prostate and pancreatic cancer, and a Phase 1/2 clinical trial for BPX-603 in HER2-positive solid tumors. We may not be able to commence clinical trials in the time frames we expect or we may encounter delays. For example, in December 2020, we announced that the FDA had placed a clinical hold on our BPX-601 trial in pancreatic cancer due to the death of a patient in the trial. Although the FDA released the hold in January 2021, there can be no assurance that future patients deaths in this or any of our clinical trials will not trigger additional clinical holds. As these product candidates are in early stages of development, we face significant uncertainty regarding whether they will be effective and safe in human patients, and the results from preclinical studies, such as in vitro and in vivo studies, of BPX-601 and BPX-603 may not be indicative of the results of clinical trials of these product candidates. For example, in October 2020, we announced that the first four pancreatic cancer patients treated with BPX-601 followed by repeat rimiducid dosing showed evidence of rimiducid-mediated CAR-T cell activation but clinically meaningful efficacy as measured by RECIST criteria was not observed. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Even if clinical trials are successfully completed, the FDA or foreign regulatory authorities may not interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of our clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

We may not be successful in our efforts to use and expand our CID platform to build a pipeline of product candidates and develop marketable products.

We believe that our CID platform, which serves as the foundation of our CaspaCIDe and GoCAR-T technologies, can be further leveraged to discover other novel technologies, therapeutic applications and market opportunities. We are at an early stage of development and our platform has not yet, and may never lead to, approved or marketable products. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including for reasons related to their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we may not be able to obtain product or partnership revenues in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical and clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities could require us to perform additional clinical trials before approving our marketing applications. It is possible that, upon inspection, such regulatory authorities could determine that any of our clinical trials fail to comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices, or cGMPs, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing preclinical,

clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

Our business could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business.

Our business could be adversely affected by health epidemics in regions in which we have operations or conduct research activities or clinical trials. Such health epidemics could also affect the business or operations of contract manufacturers, raw material suppliers, clinical trial sites, and other third parties with whom we conduct business.

For example, the effects of government stay-at-home orders or related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition. Specifically, COVID-19 related delays in clinical trial enrollment, patient care, data availability, or monitoring may delay the timeline to our integrity of data from our trials and could affect their acceptability to the FDA or other regulatory authorities, which would represent significant setbacks for the applicable program. To date, we have experienced COVID-19-related delays on patient screening and enrollment which may impact the speed of enrollment and the timing of data presentations from our ongoing studies. More significant disruptions may occur if the pandemic worsens in the geographies in which our study sites or manufacturing facilities are located. In addition, quarantines, stay-at-home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, the effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely. In addition, to the extent the ongoing COVID-19 outbreak adversely affects our business, financial condition, results of operations and growth prospects, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this “Risk Factors” section.

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial’s primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the impact of the COVID-19 pandemic;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion; and
- competing clinical trials and approved therapies available for patients.

In particular, some of our clinical trials will look to enroll patients with characteristics which are found in a very small population, for example, patients with rare cancers with specific attributes that are targeted with our product candidates. Our clinical trials will compete with other companies' clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than enroll patients in any of our future clinical trials. Patients may also be unwilling to participate in our clinical trials because of negative publicity from adverse events in the biotechnology or gene therapy industries.

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

Any adverse developments that occur during any clinical trials conducted by academic investigators, our collaborators or other entities conducting clinical trials under independent INDs may affect our ability to obtain regulatory approval or commercialize our product candidates.

Rimiducid and CaspaCIDe-containing cell therapy constructs are being used by third parties in clinical trials for which we are collaborating or in clinical trials which are completely independent of our development programs. We have little to no control over the conduct of those clinical trials. If serious adverse events occur during these or any other clinical trials using our product candidates, the FDA and other regulatory authorities may delay, limit or deny approval of our product candidate or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive regulatory approval for any product candidate and a new and serious safety issue is identified in clinical trials conducted by third parties, the applicable regulatory authorities may withdraw their approval of the product or otherwise restrict our ability to market and sell our product. In addition, treating physicians may be less willing to administer our product due to concerns over such adverse events, which would limit our ability to commercialize our product.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Adoptive cell therapy with autologous T cells is associated with a range of potentially severe immune-mediated adverse effects. In third party clinical trials involving CAR-T cells, the most prominent acute toxicities included symptoms thought to be associated with the release of cytokines, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, such as confusion, cranial nerve dysfunction and speech impairment. Adverse side effects attributed to CAR-T cells were severe and life-threatening in some patients. The life-threatening events were related to kidney dysfunction and toxicities of the central nervous system. Severe and life-threatening toxicities occurred primarily in the first two weeks after cell infusion and generally resolved within three weeks. In the past, several patients have also died in clinical trials by others involving CAR-T cells.

Undesirable side effects observed in our clinical trials, whether or not they are caused by our product candidates, could result in the delay, suspension or termination of clinical trials by us, the FDA or other regulatory authorities for a number of reasons. In addition, because the patients in our clinical trials are suffering from life-threatening diseases, are often suffering from multiple complicating conditions and are in a position of extreme immune deficiency at the time that they receive our therapy, it may be difficult to accurately assess the relationship between our product candidates and adverse events experienced by very ill patients. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on relatively new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. Costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from therapies such as our current and future product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products. In addition, our proposed product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. The costs of our clinical trials may increase if the FDA does not agree with our clinical development plans or requires us to conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Specifically, genetically engineering T cells is a competitive endeavor. Multiple companies are engaged in the engineering of T cells, including (but not limited to): 2seventy bio, Inc., Adaptimmune, Alaunos Therapeutics, Inc., Allogene Therapeutics, Inc., Amgen Inc., Atara Biotherapeutics, Inc., Athenex, Inc., Autolus Therapeutics plc, BioNTech Europe GmbH, Bristol-Meyer Squibb Co., Cellectis SA, Celyad S.A., CRISPR Therapeutics, Fate Therapeutics Inc., GlaxoSmithKline plc, Gilead Sciences, Inc., Immatics N.V., ImmunityBio, Inc., Iovance Biotherapeutics, Inc., Janssen Pharmaceutical, Legend Biotech, Lyell Immunopharma, Inc., Medigene AG, Mustang Bio, Inc., Novartis AG, Obsidian Therapeutics, Poseida Therapeutics, Precigen Inc., Precision Biosciences, Inc., Sana Biotechnology, Sorrento Therapeutics, Inc., and Takeda Pharmaceutical Co.

In addition to other cell based treatments, our product candidates may compete in their solid tumor indications with novel therapeutics of other modalities, including small molecules, monoclonal antibodies, bi-specific antibodies, antibody-drug conjugates, and targeted radionuclides.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Item 1. Business Competition" under Part I of our Annual Report.

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. Workforce and expense reductions may have an adverse impact on our internal programs, our ability to hire and retain key personnel and may be distracting to management.

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 currently employ a small number of employees and 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 substantially harm our business.

We substantially decreased our workforce in October 2020 and, depending on our need for additional funding and expense control, we may be required to implement further workforce and expense reductions in the future. Further workforce and expense reductions may not result in efficiencies and anticipated savings and could result in reduced progress on our internal programs. In addition, employees, whether or not directly affected by a reduction, may seek future employment with our business partners or

competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidentiality of certain proprietary information and knowledge may not be maintained in the course of any such future employment. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. In addition, the implementation of expense reduction programs may result in the diversion of efforts of our executive management team and other key employees, which could adversely affect our business.

Furthermore, we have identified and may continue to identify deficiencies in our internal control over financial reporting due in part to our limited staffing and resources. If we are unable to maintain effective controls over financial reporting, it is possible that a misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis. We have implemented and continue to implement measures designed to improve our internal control over financial reporting, including the retention of accounting consultants to assist in areas of complex accounting and financial reporting. However, if we are unsuccessful in maintaining the effectiveness of our internal control over financial reporting, the accuracy and timing of our financial reporting may be harmed, which could result in, among other things, restatements of our financial statements, failure to comply with SEC requirements, loss of investor confidence in our financial reporting, and a decline in our stock price.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock units, or RSUs, that vest over time. The value to employees of stock options and RSUs 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 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. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled scientific and medical personnel.

The terms of our 2019 private placement of equity restrict our operating and financial flexibility, and give priority to certain investors, both of which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.

In August 2019, we entered into an agreement with certain institutional investors providing for a private placement. Pursuant to the terms of the 2019 securities purchase agreement for the private placement transaction, the investors in the private placement transaction have consent rights over certain significant matters of our business. These include decisions to authorize or issue equity securities that are senior or pari passu to the Series 1 preferred stock with respect to liquidation preference, the occurrence of indebtedness in excess of $1,000,000, the sale or license of certain of our technology and the payment of dividends. As a result, these stockholders, acting together, will have significant influence over certain matters affecting our business. The investors in the private placement may not exercise their rights to purchase additional tranches of preferred stock and may not consent to us seeking additional funds through debt or other equity financings. In addition, potential investors in the Company may decline to do so because of the preferential rights granted under the private placement agreement. Each of these factors could negatively impact our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.

We are reliant on a third party to manufacture our clinical product candidates and may not be able to secure adequate manufacturing capacity.

In April 2020, we announced the closing of the sale of our U.S. manufacturing facility to M.D. Anderson. When M.D. Anderson assumed ownership of the facility, we became reliant on M.D. Anderson to supply our current clinical product candidates. We have endeavored to structure the transaction in a manner that ensures availability of adequate capacity and priority access thereto for the continued clinical development of our product candidates. Given the complexity of the manufacturing processes for cellular therapies, M.D. Anderson may be unable to effectively manufacture or release our products in accordance with applicable cGMP standards, which could result in significant costs or delays to our programs.

We oversee a complex manufacturing supply chain of cellular therapy product candidates, viral vectors and small molecule drugs.

Because of the complex nature of our cell therapy products, we need to oversee the manufacture of multiple components that require a diverse knowledge base and appropriate manufacturing personnel. The supply chain for these components is separate and distinct, and no single manufacturer can supply more than one component of each of our products. Additionally, it is likely that the cell therapy products will need to be made within an appropriate geographic location for the area in which the products will be utilized, so one cell therapy manufacturing facility may not be able to supply diverse geographic areas. Any lack of capabilities to store, freeze, thaw and infuse our cell therapies would adversely affect our business and prospects.

Our autologous GoCAR-T product candidates, including BPX-601 and BPX-603 are manufactured on a patient-by-patient basis using each patient's own cells. Efficient manufacturing of these products relies upon our ability to sufficiently expand and activate the cells of patients who have undergone multiple lines of prior therapy, often including immunosuppressive chemotherapy. Rimiducid, the small molecule drug used to activate both our iMC and iC9 switches, is a complex molecule to synthesize and is relatively insoluble and lipophilic, rendering it difficult to formulate. We have limited internal expertise in small molecule drug development and manufacturing, and we have identified specialty contract manufacturers to produce the rimiducid drug substance and drug product. It is uncertain whether the drug substance and drug product manufacturers will be able to manufacture sufficient quantity and quality of rimiducid to conduct the necessary non-clinical and clinical trials.

We have not yet caused our product candidates to be manufactured or processed on a commercial scale. We may not be able to scale patient-by-patient manufacturing and processing to satisfy clinical or commercial demands for any of our product candidates. In addition, our anticipated reliance on a limited number of third-party manufacturers for manufacturing exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and any replacement contractor must be approved by regulatory authorities. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory approval, if any.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by regulatory agencies to ensure strict compliance with cGMP and other government regulations and standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We have limited information available regarding the ultimate cost of our products, and cannot estimate what the cost of our products will be upon commercialization, should that occur.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product. Because of the patient-specific nature of our manufacturing process, it is not amenable to traditional "scale up" to manufacture larger lots as is performed for traditional drugs and biological agents.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Gene-modified cell therapy manufacture requires many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. Some suppliers typically support biomedical researchers or blood-based hospital businesses and may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have commercial supply arrangements with many of these suppliers and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls; and
- business interruptions resulting from geo-political actions, including war and terrorism, and the impact of the COVID-19 pandemic.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations and enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, 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. If we license products or businesses, 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. It is possible that, following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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 manufacture our drug substance and product, and because we collaborate with various organizations and academic institutions on the advancement of our technology platform, we must, at times, 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, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees 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, such as trade secrets. Despite these contractual provisions, 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 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.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for 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 for product candidates 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 relinquish valuable rights to that product candidate through strategic 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, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We and our contractors utilize hazardous materials in our business operations, and any claims relating to improper handling, storage, or disposal of these materials could harm our business.

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

Our internal computer systems, or those used by our clinical investigators, contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

System outages, network disruptions and cyber-security threats could interrupt the operation of our business.

We are dependent on the use of information technology systems for our operations. Outages, disruptions and threats could have an adverse impact on our ability to conduct operations. Cyber-security threats, such as malware, phishing and network attacks, are on the rise. These attacks can affect the availability of our information technology systems, including their data, as well as the confidentiality and integrity of these systems. A security breach poses a risk to confidential data, including but not limited to intellectual property and trade secrets resulting in financial, legal or reputational harm to us. Insider threats may exist if an individual authorized to access our technology systems improperly discloses sensitive data to unauthorized persons or the public. We also have outsourced elements of our operations, including elements of our information technology infrastructure, and thus manage several independent vendor relationships with third parties who may have access to our confidential information. Confidentiality agreements are in place for authorized users and third parties to support the prevention of confidential information being improperly disclosed. We have policies and procedures in place, including controls around the access and activity of authorized users, active system monitoring, back-up and recovery, information technology security and mandatory annual information technology security awareness training to assist in the prevention and mitigation of an outage, disruption or threat. In addition, we have invested in high availability, redundant technologies that will reduce the risk of an outage, disruption or threat. However, our efforts may not prevent an outage, disruption or threat that would materially adversely affect us. We also may not have sufficient liability insurance, either type or amount, to cover us against claims related to a cyber-security threat.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our clinical investigators, contractors and consultants, could be subject to power shortages, telecommunications failures, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient by patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. In particular, certain third-party manufacturers may be unable to comply with their contractual obligations to us due to disruptions caused by COVID-19, including reduced operations or headcount reductions, or otherwise, and in certain cases we may have limited recourse if the non-compliance is due to factors outside of the manufacturer’s control.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalties law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health and Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information and their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as require certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by such physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, including the European Union General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018, and which imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects.

Additionally, we are subject to state and foreign equivalents of each of the U.S. healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. We may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. For example, in May 2019, we were added as an additional defendant in an ongoing civil tort lawsuit in federal court in Los Angeles, California. The complaint alleges claims for wrongful death, negligence, breach of fiduciary duty, fraud, medical battery on decedent, medical battery on individual plaintiffs, products liability-failure to warn, breach of express warranty and products liability design or manufacturing defect. Claims could also be asserted under state consumer protection acts. We have filed a demurrer and motion to strike the fourth amended complaint, which is not currently set for hearing but will be rescheduled pursuant to a further order from the court. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, federal or state liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

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

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

As of December 31, 2021, we had aggregate U.S. net operating loss carryforwards of approximately $478.0 million, and aggregate U.S. federal and Texas state research and development credits of approximately $13.0 million and $5.1 million, respectively. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. U.S. federal net operating loss carryforwards generated in taxable years beginning before January 1, 2018, may be carried forward only 20 years to offset future taxable income, if any. Under current U.S. federal income tax law, U.S. federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such net operating loss carryforwards in taxable years beginning after December 31, 2020, is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to federal law.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced one or more ownership changes in the past, including with respect to our August 2019 public offering, and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our

control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Government Regulation

The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a BLA to the FDA, or similar approval filings to other foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. It must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, FDA's Office of Tissues and Advanced Therapies, or OTAT, has limited experience with combination products that include a small molecule component. Approval of our GoCAR-T product candidates, will likely require this FDA office to consult with other divisions of the FDA, which may result in further challenges in obtaining regulatory approval, including in developing final product labeling. The regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol, failing to follow GCPs, or dropping out of a clinical trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, or recommended for termination by the Data Monitoring Committee for such clinical trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, in December 2020 we announced that the FDA had placed a clinical hold on our BPX-601 trial in pancreatic cancer due to the death of a patient in the trial. Although the FDA released the hold in January 2021, there can be no assurance that future patients' deaths in this or any of our clinical trials will not trigger additional clinical holds. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the EU or U.S., including additional preclinical studies or clinical trials. Studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the EU and U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties and/or withdrawal of product approval if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, 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 our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- suspension or termination of manufacturing at one or more manufacturing facilities;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Foreign legislative changes may also affect our ability to commercialize our product candidates. Effective as of May 25, 2018, the GDPR imposes privacy and security obligations on any entity that collects and/or processes personal information from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community.

The use of engineered T cells as potential cancer treatments is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community. Many factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;

- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the extent and quality of the clinical evidence supporting the efficacy and safety of our product candidates;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the pricing of our product candidates and the availability of adequate reimbursement by third-party payors and government authorities;
- the willingness and ability of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- confusion or lack of understanding regarding the effects of rimiducid and the timing and size of dosing of rimiducid after immune cell therapy; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such clinical trials to demonstrate that these therapies are safe and effective may limit market acceptance our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Market acceptance and sales of our product candidates will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, successful commercialization of our products will depend in part on the availability of governmental and third-party payor reimbursement for the cost of our product candidates and/or payment to the physician for administering our product candidates. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. One third-party payor’s decision to cover a particular medical product or service does not assure that other payors will also provide coverage for the medical product or service, or to provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. Further, a third-party payor’s decision to provide coverage for a medical product or service does not imply that an adequate reimbursement rate will be approved. The market for our product candidates will depend significantly on access to third-party payors’ formularies or lists of treatments for which third-party payors provide coverage and reimbursement. Third party payors may also have difficulty in determining the appropriate coverage of our product candidates, if approved, due to the fact that they are combination products that include a small molecule drug, rimiducid.

Third-party payors establish coverage and reimbursement policies for new products, including our product candidates. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for treatments based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the EEA and other significant or potentially significant markets for our product candidate, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in Canada and the EEA will put additional pressure on product pricing, coverage, reimbursement and utilization, which may adversely affect our product sales and results of operations. These pressures can arise from policies and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following: (i) an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; (ii) an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively; (iii) a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to 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; (iv) extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (v) expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; (vii) expansion of health care fraud and abuse laws, including the federal civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; and (viii) a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive judicial and Congressional challenges to other aspects of the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA 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 PPACA-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. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA 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 PPACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2018, will remain in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through December 31, 2022 unless additional Congressional action is taken. 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. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers.

Further, recently there has been heightened governmental scrutiny in the United States over the manner in which drug manufacturers set prices for their marketed products, in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed federal 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 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, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule and guidance on September 24, 2020, 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 Medicare 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 pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation, or MFN, 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 MFN model, on December 27, 2021, CMS published a final rule that rescinded the MFN 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 are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional federal and state healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or other adverse effects on our business. For example, it is possible that additional governmental action is taken to address the COVID-19 pandemic.

We expect that additional federal and state healthcare reform measures, such as further amendments and changes to the PPACA will be adopted in the future, any of which could result in reduced demand for our products or other adverse effects on our business.

Certain countries have a very difficult reimbursement environment and we may not obtain reimbursement or pricing approval, if required, in all countries where we expect to market a product, or we may obtain reimbursement approval at a level that would make marketing a product in certain countries not viable.

We expect to experience pricing pressures in connection with the sale of any products that we may develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Due to the novel nature of our technology and the small size of our target patient populations, we face uncertainty related to pricing and reimbursement for these product candidates.

Our target patient populations for our potential product candidates are relatively small, as a result, the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial and manufacturing infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to our product candidates, for example,

reimbursement for administration of our product candidates to patients, is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products.

We are subject to extensive laws and regulations related to data privacy, and our failure to comply with these laws and regulations could harm our business.

We are subject to laws and regulations governing data privacy and the protection of personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the European Union is governed by the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third-party transactions, but also to transfers of information within our company, including employee information. The GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third-party service providers process, including in clinical trials conducted in the United States and European Union. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Additionally, California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act, or the CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. As of January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. As currently written, the CCPA will likely impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

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

Among other matters, Trade Laws prohibit companies and their employees, agents, clinical research organizations, 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 engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We also expect our non-U.S. activities to increase in time. 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.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other

collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, 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, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those 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 drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We license from Baylor College of Medicine, or Baylor, certain intellectual property related to methods for activating antigen presenting cells, to certain genetic constructs and to certain methods for inducing apoptosis. Baylor may terminate or modify our licenses in the event of a material breach by us that remains uncured following the date that is 90 days after written notice of such breach or upon certain insolvency events that remain uncured following the date that is 30 days following written notice of such insolvency event. In addition, we have funded certain of our clinical development activities and may fund certain of our future clinical development with funds from the State of Texas. The State of Texas may have rights to commercialize the results of those clinical trials if it determines that we have failed, after notice and an opportunity to cure, to use diligent and commercially reasonable efforts to commercialize or otherwise bring to practical application the results of the funded clinical trials. We are also dependent on our license agreements with Agensys, Inc. (a subsidiary of Astellas Pharma, Inc.) with respect to PSCA-targeted CARs, and BioVec Pharma Inc. with respect to making retrovirus for all of our programs. The termination of any of these licenses could have a material adverse effect on our business.

Any termination of these agreements, or other agreements to which we are a party could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and our licensors and other partners regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- 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.

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. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If our efforts to protect the proprietary nature of our technologies are not adequate, we may not be able to compete effectively in our market.

Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Certain intellectual property which is covered by our in-license agreements has been developed at academic institutions which have retained non-commercial rights to such intellectual property.

There are several pending U.S. and foreign patent applications in our portfolio, and we anticipate additional patent applications will be filed both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property. We cannot be certain that the claims in our pending patent applications directed to compositions of matter for our product candidates will be considered patentable by the U.S. Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries. Method of use patents have claims directed to 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 strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. or in other foreign countries. Even if the patents do successfully issue, 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. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, it is possible that patent applications in our portfolio may not be the first filed patent applications related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U.S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a “first to file” system in the U.S. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements; however, it is possible that our trade secrets and other confidential proprietary information could be disclosed or that competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent

unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including inter parties review and post grant review have been implemented. As stated above, this reform is untried and untested and will bring uncertainty to the possibility of challenge to our patents in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents, of which we are currently unaware or have not sufficiently analyzed with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, methods of use, including combination therapy or patient selection methods or any final product itself, the holders of any such patents may be able to block our ability to develop and commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. It is possible that any such license would not be available at all or on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

For example, we are aware of a third-party patent having claims directed to chimeric DNA comprising DNA segments encoding (1) a single chain antibody domain and (2) transmembrane and cytoplasmic domains of an endogenous protein. Even though we have reason to believe that our product candidates are not covered by claims of this patent, an owner or licensee of the patent still might bring a patent infringement suit against us. If the patent is asserted against us, we may not prevail in defending against claims of infringement and/or challenging the validity of claims in the patent. We may not successfully develop alternative technologies or enter into an agreement by which we obtain rights to the patent. These rights, if necessary, may not be available on terms acceptable to us.

We are aware of third-party patents having claims that may be considered as being directed to single-chain antibody fragments that bind to PSCA and these patents may be considered relevant to BPX-601 and related technologies we are developing. We currently are evaluating whether or not we need to obtain rights to these patents under a license, and if it is determined that we need to obtain such rights, whether these rights can be obtained. We are also aware of third-party patent applications having claims that may be considered as being directed to cellular therapy constructs utilizing a heterodimer domain for activation of caspase 9. We are monitoring these applications and if they are granted with the claims as drafted, they may be relevant to our potential dual-switch product candidates containing such a heterodimer activation domain.

Also, while we are aware there are other third-party patents having claims that may be considered relevant to technologies for which we are seeking, or plan to seek, regulatory approval, we believe those patents have a patent term that may expire prior to the time we expect to obtain regulatory approval for these technologies. The estimated expiration dates for those patents were determined according to information on the face pages of the patents, and certain factors that could influence patent term, such as patent term adjustment and patent term extension, for example, were not factored into these estimates. Accordingly, the estimated

expiration dates of those patents may not be accurate and one or more of those patents may not expire before we obtain regulatory approval for an applicable technology. Owners or licensees of one or more of those patents may bring a patent infringement suit against us. If one or more of those patents are asserted against us, we may be able to assert a defense for a safe harbor to patent infringement under 35 U.S.C. 271(e)(1) if certain requirements are met. It is possible that (1) certain of these requirements may not be met, and/or (2) one or more of the third-party patents might expire after one or more of our technologies obtain regulatory approval, and consequently we may not successfully assert such a defense to patent infringement. If we are unsuccessful in asserting a defense under 35 U.S.C. 271(e)(1), it is possible we may not prevail in defending against claims of infringement and/or challenging the validity of claims in those patents. We may not successfully develop alternative technologies or enter into agreements by which we obtain rights to applicable patents. These rights, if necessary, may not be available on terms acceptable to us.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. 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.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may not be able to successfully complete negotiations and ultimately acquire the rights to the intellectual property that we may seek to acquire in the future.

We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. It also is possible that a competitor we sue for patent infringement could countersue us for allegedly infringing one or more of their own patents or one or more patents they licensed from another entity. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. It also is possible that third parties could institute a patent office post-grant proceeding against one or more of our patents, or one or more patents licensed to us, such as a post grant review proceeding, inter parties review proceeding or reexamination proceeding at the USPTO, or an opposition proceeding in a jurisdiction outside the U.S. An unfavorable outcome in a post-grant proceeding could result in a loss of our patent rights. Litigation, interference proceedings or patent office post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We also may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could 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 substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse 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. Noncompliance 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. Such noncompliance events are outside of our direct control for (1) non-U.S. patents and patent applications owned by us, and (2) patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions, for example, opposition proceedings. Any such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art and that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patents directed to our product candidates. A loss of patent rights could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, 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 recent 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.

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

We have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, 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. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. 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 lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Certain countries in Europe and 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. 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.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Ownership of our Common Stock

If we fail to satisfy applicable listing standards, our common stock may be delisted from the Nasdaq Capital Market.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. On May 5, 2021, we were notified by The Nasdaq Stock Market LLC ("Nasdaq"), that we were in breach of Listing Rule 5450(b)(2)(A), for continued listing on The Nasdaq Capital Market because the market value of our listed securities for 30 consecutive business days had been less than $35 million. On December 10, 2021, we were notified by Nasdaq that we had regained compliance with Listing Rule 5550(b)(1), which requires stockholders' equity of at least $2.5 million for continued listing of our common stock. Accordingly, we regained compliance with the continued listing requirements of The Nasdaq Capital Market.

Although we were able to regain compliance with the continued listing requirements of The Nasdaq Capital Market, we cannot assure you that we will be able to do so in the future. If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing.

In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter

certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, the price of our common stock may decline, and although our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if we are delisted, we would incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our shareholders to sell our common stock in the secondary market.

The price of our stock is volatile and you could lose all or part of your investment.

The trading price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including market conditions in general and a limited trading volume for our shares. In addition to the factors discussed in this "Risk Factors" section and elsewhere in our Annual Report, these factors include:

- the commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in our ongoing or future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our CID technology platform and our small molecule drug rimiducid;
- adverse developments concerning our contract manufacturers;
- changes in the structure of healthcare payment systems;
- our inability to maintain successful collaborations or to establish new collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of diseases and cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

Our principal stockholders own a significant percentage of our stock and can exert significant control over matters subject to stockholder approval.

Holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant portion of our voting stock, including shares subject to outstanding options. As a result, if these shareholders were to choose to act together, they would have the ability to significantly influence all matters requiring stockholder approval. For example, these stockholders may be able to significantly influence 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 feel are in your best interest as one of our stockholders.

Changes in accounting rules, assumptions and/or judgments could materially and adversely affect us.

Accounting rules and interpretations for certain aspects of our operations are highly complex and involve significant assumptions and judgment. These complexities could lead to a delay in the preparation and dissemination of our financial statements. Furthermore, changes in accounting rules and interpretations or in our accounting assumptions and/or judgments, such as asset impairments, could significantly impact our financial statements. In some cases, we could be required to apply a new or revised standard retroactively, resulting in restating prior period financial statements. Any of these circumstances could have a material adverse effect on our business, prospects, liquidity, financial condition and results of operations.

Our consolidated financial statements, including our liabilities and statements of operations are subject to quarterly changes in our accounting of our outstanding Series 1 Preferred Stock and related warrants.

In accordance with ASC Topic 815, *Accounting for Derivative Instruments and Hedging Activities*, and ASC Topic 480, *Liabilities-Distinguishing from Equity*, convertible preferred shares are accounted for as temporary equity and warrants are accounted for as liabilities at their fair value during periods where they can be net cash settled in case of a change in control transaction. The warrants are accounted for as a liability at their fair value at each reporting period. The value of the derivative warrant liability is re-measured at each reporting period with changes in fair value recorded in earnings. To derive an estimate of the fair value of these warrants, the binomial model is utilized, adjusted for the effect of dilution, which embodies all of the requisite assumptions (including trading volatility, estimated terms, dilution and risk-free rates) necessary to determine the fair value of these instruments. This process requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. As a result, our consolidated financial statements and results of operations may fluctuate quarterly, based on factors, such as the trading value of our common stock and certain assumptions, which are outside of our control. Consequently, our liabilities and consolidated statements of operations may vary quarterly, based on factors other than our revenues and expenses. The liabilities and accounting line items associated with our derivative securities on our balance sheet and statement of operations are non-cash items, and the inclusion of such items in our financial statements may materially affect the outcome of our quarterly and annual results, even though such items are non-cash and do not affect the cash we have available for operations. Investors should take such derivative

accounting matters and other non-cash items into account when comparing our quarter-to-quarter and year-to-year operating results and financial statements.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Certain holders of our outstanding shares of common stock, are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Any sales of these shares by such stockholders could have a material adverse effect on the trading price of our common stock.

We register on Form S-8 all shares of common stock that are issuable under our 2019 Equity Incentive Plan, as amended, or the EIP. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our EIP and shelf registration statement, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities and costs associated with operating a public company. To raise capital, 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, including pursuant to our shelf registration statement on Form S-3 that we filed with the SEC. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. For example, in December 2021 we completed a private placement pursuant to which we issued pre-funded warrants to purchase an aggregate of 20,559,210 shares of our common stock and accompanying warrants to purchase an aggregate of 2,055,920 shares of common stock, and our outstanding shares of common stock as of March 21, 2022 was 8,552,207. This transaction resulted, and any similar future transactions may also result, in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the existing holders of our common stock.

We completed a public offering of our Series 1 preferred stock on August 21, 2019, and if we are required to redeem shares of preferred stock, our cash position will be negatively impacted. In addition, we may not have sufficient funds to redeem such shares of preferred stock.

We issued 575,000 shares of Series 1 preferred stock in connection with our August 2019 public offering. Subject to the terms of our certificate of incorporation, at any time on or after August 21, 2024, some or all of our outstanding shares of preferred stock will be redeemable at the option of the holder at a redemption price of $100.00 per share of Series 1, upon delivery of an irrevocable written notice to us. If a holder of preferred stock requests redemption we will be required to redeem such shares of preferred stock. However, we may be unable to redeem such preferred stock if restrictions under applicable law or contractual obligations prohibit such redemption. For example, Delaware law provides that a redemption on capital stock may only be paid from “surplus” or, if there is no “surplus,” from a corporation’s net profits for the then-current or the preceding fiscal year. Unless we operate profitably, our ability to redeem the preferred stock would require the availability of adequate “surplus,” which is defined as the excess, if any, of our net assets (total assets less total liabilities) over our capital. To date, we have operated at a loss. Accordingly, if we do not have sufficient “surplus” under Delaware law, we would be unable to effect such redemption. If we do have sufficient “surplus” to effect such redemption, our available cash will be negatively impacted and our ability to use the net proceeds from this offering could be substantially limited. In addition, such reduction in our available cash could decrease the trading price of our common stock, and, accordingly, the preferred stock and our warrants.

Certain investors in the 2019 private placement will have the ability to control or significantly influence certain business decisions.

Pursuant to the terms of the 2019 securities purchase agreement for the private placement transaction, certain investors in the private placement transaction have consent rights over certain significant matters of the Company’s business. These include decisions to authorize or issue equity securities that are senior or pari passu to the Series 3 preferred stock with respect to liquidation preference, the incurrence of indebtedness in excess of $1,000,000, the sale or license of the Company’s iMC switch

technology and the payment of dividends. As a result, these stockholders, acting together, will have significant influence over certain matters affecting our business.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.*

Our amended and restated certificate of incorporation and our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

These provisions 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.

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 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event securities or industry analysts that cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

During 2021, the Company exited its Houston and South San Francisco office facilities and the leases were terminated. As of December 31, 2021, the Company had no physical properties.

ITEM 3. Legal Proceedings

The information set forth under the “Litigation” subheading in Note 8 - Commitments and Contingencies of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K is incorporated herein by reference.

ITEM 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "BLCM".

Holders of Record

As of March 21, 2022, there were 14 stockholders of record of our common stock. Certain shares are held in "street" name and thus the actual 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 to support our operations and finance the growth and development of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

ITEM 6. [Reserved]

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

The following discussion and analysis should be read in conjunction with the financial statements and related notes included in "Item 8 - Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

On February 5, 2020, we filed a Certificate of Amendment of the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to (i) effect a reverse stock split of all issued and outstanding shares of our common stock at a ratio of 1-for-10 and (ii) reduce the number of authorized shares of our common stock from 200,000,000 to 40,000,000.

On February 5, 2020, we effected a reverse stock split of all issued and outstanding shares of our common stock at a ratio of 1-for-10, and reduced the number of authorized shares of our common stock from 200,000,000 to 40,000,000. Share related amounts have been retroactively adjusted in this Annual Report on Form 10-K to reflect this reverse stock-split for all periods presented.

Overview

We are a clinical stage biopharmaceutical company focused on discovering and developing novel, controllable cellular immunotherapies for various forms of cancer, including both hematological cancers and solid tumors. We are advancing CAR-T cell therapies, which are an innovative approach in which a patient's or donor's T cells are genetically modified to carry chimeric antigen receptors, or CARs. We are using our proprietary Chemical Induction of Dimerization, or CID, technology platform to engineer our product candidates with switch technologies that are designed to control components of the immune system in real time. By incorporating our CID platform, our product candidates may offer better efficacy and safety outcomes than are seen with current cellular immunotherapies. For additional information about our business, and candidate development programs, see the discussions contained within "Item 1. Business" in this Annual Report.

Results of Operations

The following table sets forth our results of operations for the periods indicated:

(in thousands)	Year Ended December 31, 2021	December 31, 2020	Change
Revenues			
Supply agreement	$ 700	$ —	$ 700
License revenue	5,500	500	5,000
Total revenues	$ 6,200	$ 500	$ 5,700
Operating expenses:			
Research and development	23,578	39,052	(15,474)
General and administrative	7,010	15,531	(8,521)
Total operating expenses	30,588	54,583	(23,995)
Other operating income (expense)			
Impairment of property and equipment	—	(1,265)	1,265
(Loss) Gain on dispositions, net	(478)	3,656	(4,134)
Total other operating income (expense)	(478)	2,391	(2,869)
Loss from operations	(24,866)	(51,692)	26,826
Other income (expense):			
Interest income	32	387	(355)
Interest expense	(4)	(2,659)	2,655
Change in fair value of warrant and private placement option liabilities	15,126	46,130	(31,004)
Gain on extinguishment of debt	—	112	(112)
Other income	7	—	7
Total other income	15,161	43,970	(28,809)
Net loss	$ (9,705)	$ (7,722)	$ (1,983)

Revenues

The increase in revenues for the year ended December 31, 2021, compared to last year, was due to agreements executed with external parties during the year. In the first quarter of 2021, we entered into a multi-year supply agreement with Takeda Development Center Americas, Inc. (Takeda) for the supply of rimiducid for potential use in clinical trials of TAK-007 (CD19 CAR-NK cell therapy). The supply was fulfilled in the second quarter of 2021 generating revenue of $0.7 million. In the third quarter of 2021, we entered into an option and license agreement with The University of Texas M. D. Anderson Cancer Center (“MD Anderson”) for certain option and license rights to CaspaCIDe and related technologies. An upfront fee under the agreement of $5.0 million was recognized as revenue, together with $0.5 million of annual license fee under a previous license agreement with MD Anderson. For the year ended December 31, 2020, the only source of revenue was the annual license fee of $0.5 million.

Research and Development Expenses (R&D)

The decrease in R&D expenses for the year ended December 31, 2021, compared to the year ended December 31, 2020, was primarily due to reduced expenses related to rivo-cel related activities, the sale of the manufacturing facility, and the reduction in force that was implemented in the fourth quarter of 2020, partially offset by an increase in expenses related to our GoCAR-T programs. This resulted in $12.3 million reduction in salaries, benefits, travel, and share based compensation related charges and a $3.2 million reduction in general R&D supplies, technical operations and pharmaceutical development expenses and facility charges primarily due to lower clinical trial activities. Additionally, depreciation expense decreased $0.1 million due to the manufacturing facility and related laboratories disposed of in April 2020 and additional laboratory assets and equipment sold in March 2021.

General and Administrative Expenses (G&A)

The decrease in G&A expenses for the year ended December 31, 2021, compared to the year ended December 31, 2020, was primarily due the aforementioned reduction in force that reduced employee-related charges by $6.8 million as well as the reduction in rivo-cel related commercialization activities that reduced charges by $1.7 million.

Impairment

In connection with the Company's restructuring plan, the management elected to seek an exit to its leased R&D facility in Houston, Texas during the fourth quarter of 2020. As a result, we reclassified the assets and liabilities associated with the leased facility as held for sale, which included a right-of-use asset of $0.5 million, and property plant and equipment of $2.3 million. Based on the cost to exit the lease and the net realizable value of the related assets, we recognized an impairment charge of $1.3 million for the year ended December 31, 2020. The sale of the assets and equipment was completed in the first quarter of 2021, and there was no additional impairment recognized for the year ended December 31, 2021.

Gain on dispositions, net

The decrease in gain of dispositions, net for the year ended December 31, 2021, compared to last year, was primarily due to the disposal of the clinical supply manufacturing facility to MD Anderson in the second quarter of 2020 which resulted a gain of $3.7 million in 2020. In addition, there was a loss on termination of the South San Francisco office space of $0.5 million during the first quarter of 2021.

Other Income (Expense)

Other income or expense primarily consists of interest income, interest expense, and changes in fair values of our warrant liability and the private placement option, which are remeasured at each reporting period. Due to the nature of the inputs in the model used to assess the fair value of the warrant liability and private placement option, we may experience significant fluctuations at each reporting period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in stock price volatility over the remaining term of the warrants and options.

The decrease in other income for the year ended December 31, 2021, was primarily due to a decreased gain of $15.1 million from the change in fair value of our warrant and private placement option liabilities, compared to a gain from change in fair value of $46.1 million for the year ended December 31, 2020. The bigger change in fair value over 2020 was primarily driven by a more significant decrease in our stock price compared to 2021. Meanwhile, there is a decrease of $3.0 million in interest expense for the year ended December 31, 2021 compared to last year, as a result of the early retirement of the Oxford Loan in 2020.

Liquidity and Capital Resources

Sources of Liquidity

At December 31, 2021, we had cash, cash equivalents, and restricted cash of $47.7 million and net cash used in operations of approximately $23.1 million for the year ended December 31, 2021. Notably, in December 2021, we completed a private placement equity financing transaction for gross proceeds of approximately $35.0 million before deducting placement agent commissions and offering expenses.

The accompanying consolidated financial statements have been prepared on the basis that there is no substantial doubt about our ability to continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. Our cash resources are primarily consumed by operating activities and we expect negative cash flows from operations to continue for at least the next 12 months. We do not have any material contractual obligations or commitments as of December 31, 2021. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, legal and other regulatory expenses, and general overhead costs. Based on our current research and development plans and our timing expectations related to the progress of our programs, we believe that our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least mid-2023.

We plan to continue attempting to obtain future financing and/or engage in strategic transactions, but we cannot predict, with certainty, the outcome of our actions to generate liquidity, including the availability of additional equity or debt financing, or whether such actions would generate the expected liquidity as currently planned. To continue as a going concern, we may postpone or eliminate some of our research and development programs and reduce our administrative costs. We may also intend to seek additional funding including, but not limited to, any or all of the following potential sources:

We have an effective shelf registration statement on Form S-3 for the offer and sale of up to $400.0 million of our securities, of which approximately $317.5 million remains available for future offerings. We may pursue additional funding through the sale of our securities in one or more offerings under this registration statement; however, we cannot assure you that we will be able to do so on favorable terms. Our ability to offer and sell our securities in a primary offering on our Form S-3 is currently limited by Instruction I.B.6 of Form S-3, commonly referred to as the "baby shelf" limitation. If we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that could adversely affect the rights of our existing stockholders. If we raise additional capital through the issuance of debt securities, we could incur fixed payment obligations and become subject to certain restrictive covenants, including limitations on

our ability to incur additional debt and acquire or license intellectual property rights, and other operating restrictions that could restrict our ability to conduct our business.

In addition, we may receive additional capital through the exercise of outstanding warrants to purchase our stock if our stock price sufficiently increases. As of December 31, 2021, warrants to purchase 5,750,000 shares of our Series 1 preferred stock at an exercise price of $130.00 per share (equivalent to $13.00 per share of common stock), warrants to purchase 4,149,378 shares of our common stock at an exercise price of $6.50 per share and warrants to purchase 2,055,920 shares of our common stock at an exercise price of $1.69 per share were outstanding. The preferred stock warrants expire on August 21, 2026 and the common warrants expire on November 3, 2025 and December 7, 2028, respectively.

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility, including 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. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. Moreover, if we do not obtain such additional funds, there could be substantial doubt about our ability to continue as a going concern and increased risk of insolvency, which could result in a total loss of investment to our stockholders and other security holders.

Cash Flows

Operating Activities

Net cash used in operating activities during the year ended December 31, 2021, was $23.1 million compared to $56.7 million for the year ended December 31, 2020. The primary operating activities during 2021 were (1) $9.7 million of net losses, (2) a $15.1 million non-cash gain from change in fair market value of warrant derivative and private placement option liabilities, (3) a $2.4 million decrease from operating assets and liabilities, and (4) a $0.5 million of loss on dispositions, net. These activities were partially offset by share-based compensation charges of $3.4 million and other smaller non-cash items.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2021, was $0.9 million compared to $14.1 million for the year ended December 31, 2020. The net cash provided by investing activities during the year ended December 31, 2021, was primarily due to $0.9 million of net proceeds received from the sale of property and equipment. The $14.1 million of net cash provided by investing activities during 2020 was also related to proceeds from the sale of property and equipment.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2021, was $32.9 million compared to net cash used of $14.2 million for the year ended December 31, 2020. The net cash provided by financing activities during the year ended December 31, 2021 was generated from the issuance of pre-funded warrants during the private placement closed in December 2021, net of offering expenses. The net cash used in financing activities for the year ended December 31, 2020 was primarily due to the principal payments and the subsequent early retirement of debt totaling $37.1 million partially offset by proceeds from the issuance of common stock and pre-funded warrants, net in the amount of $22.9 million.

As of December 31, 2021, we do not have any short-term or long-term lease liabilities, debt obligations or other material capital commitments. The expected capital expenditures for the next 12 months are minimal.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources. We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for any other contractually narrow or limited purpose.

Critical Accounting Policies and Significant Estimates

Management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which are prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to

be reasonable under the circumstances. In many instances, we could have reasonably used different accounting estimates, and in other instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from management's estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. While our significant accounting policies are described in the notes to our financial statements, we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies related to the more significant areas involving management's judgments and estimates. Our management has discussed the development and selection of these critical accounting estimates with the audit committee of our board of directors and the audit committee has reviewed the company's disclosure relating to it in this MD&A.

Warrant Derivatives

Freestanding public warrants exercisable for multiple underlying instruments are classified as liabilities. The Company accounts for these warrants in accordance with ASC Topic 480, *Distinguishing Liabilities From Equity* ("ASC 480") and ASC Topic 815, *Accounting for Derivative Instruments and Hedging Activities* ("ASC 815"). The Company estimates the fair value of these liabilities using the binomial option model. The option pricing model of our warrant derivative liabilities are estimates and are sensitive to changes to certain inputs used in the pricing model. See Note 1 - Organization, Basis of Presentation, and Summary of Significant Accounting Policies for a discussion of how the Company accounts for its warrant derivatives.

Freestanding pre-funded warrants and accompanying warrants exercisable for multiple underlying instruments are classified as equity. The Company accounts for these warrants in accordance with ASC Topic 480, *Distinguishing Liabilities From Equity* ("ASC 480") and ASC Topic 815, *Accounting for Derivative Instruments and Hedging Activities* ("ASC 815"). Upon the issuance of pre-funded warrants or the exercise of its accompanying common warrants, the Company receives proceeds from its investors which are recognized as equity. Furthermore, because pre-funded warrants and accompanying warrants do not participate in dividends with common stockholders, they are not considered a participating security in its current form and, therefore, they will be considered in the Company's basic and diluted EPS calculations (if in net income position). See Note 1 - Organization, Basis of Presentation, and Summary of Significant Accounting Policies for a discussion of how the Company accounts for its pre-funded warrants.

Private Placement Option

The Company previously entered into a 2019 securities purchase agreement that contained a call option on preferred shares that are puttable outside the control of the Company. The Company accounted for the option in accordance with ASC Topic 480, *Distinguishing Liabilities From Equity* ("ASC 480") and ASC Topic 815, *Accounting for Derivative Instruments and Hedging Activities* ("ASC 815"). The Company estimated the fair value of the liability using a binomial lattice model, which is sensitive to changes to certain inputs. See Note 1 - Organization, Basis of Presentation, and Summary of Significant Accounting Policies for a discussion of how the Company accounted for its private placement option derivative. The private placement option was terminated on December 4, 2021, in connection with the 2021 securities purchase agreement.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for research and development employees and consultants, facilities expenses, overhead expenses, cost of laboratory supplies, manufacturing expenses, fees paid to third parties and other outside expenses. We accrue for costs incurred as the services are being provided by monitoring the status of the clinical trial or project and the invoices received from our external service providers. We adjust our accrual as actual costs become known. See Note 1 - Organization, Basis of Presentation, and Summary of Significant Accounting Policies for a discussion of how the Company accounts for research and development expenses.

Share-Based Compensation

The Company's share-based awards include stock option grants and restricted stock awards. The estimated fair value for stock options, which determines the Company's calculation of compensation expense, is based on the Black-Scholes pricing model, which requires a number of estimates, including the expected lives of awards, interest rates, stock volatility and other assumptions. Additionally, we apply a forfeiture rate to estimate the number of grants that will ultimately vest, as applicable, and adjust the expense as these awards vest. See Note 1 - Organization, Basis of Presentation, and Summary of Significant Accounting Policies for a discussion of how the Company accounts for share-based compensation.

Recently Issued Accounting Pronouncements

See Note 1 - Organization, Basis of Presentation, and Summary of Significant Accounting Policies for discussion regarding recent accounting pronouncements.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide information typically disclosed under this item.

ITEM 8. Financial Statements and Supplementary Data

Index to Financial Statements

The financial statements of Bellicum Pharmaceuticals, Inc. listed below are set forth in Item 8 of this Annual Report for the year ended December 31, 2021:

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Bellicum Pharmaceuticals, Inc.

Opinion on the Financial Statements

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

Basis for Opinion

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

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

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

Critical Audit Matter

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

Warrant liability valuation of Bellicum Pharmaceuticals

Description of the Matter	The Company's warrant derivative liability is remeasured at fair value on each balance sheet date and is valued at $2.8 million as of December 31, 2021. As explained in Note 1 to the consolidated financial statements, the Company holds freestanding warrants that are exercisable for multiple underlying instruments that are potentially redeemable. Auditing management's calculation of estimated fair value remeasurement of the warrant derivative liability was complex and judgmental due to the use of a complex valuation model and the level of uncertainty involved in management's assumptions used in the measurement process. In particular, management was required to estimate a volatility assumption at December 31, 2021.
How We Addressed the Matter in Our Audit	Our substantive audit procedures included, among others, evaluating the methodology and testing the significant assumption stated above and the accuracy and completeness of the underlying data used in management's warrant derivative liability valuation assessment. To test the volatility, we compared the assumption to historical information and performed a sensitivity analysis to evaluate the impact of changes in the fair value estimate that would result from changes in the underlying assumption. We also involved our valuation specialists to assist in the evaluation of the complex valuation model and the volatility assumption in the fair value estimate.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2014.

Houston, Texas

March 24, 2022

Bellicum Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except par value and share data)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,156	$ 35,495
Restricted cash	1,501	1,501
Accounts receivable, interest and other receivables	205	2
Prepaid expenses and other current assets	1,269	802
Assets held for sale	—	1,643
Total current assets	49,131	39,443
Operating lease right-of-use assets	—	645
Property and equipment, net	12	189
Other assets	—	307
Total assets	$ 49,143	$ 40,584
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 90	$ 891
Accrued expenses and other current liabilities	3,849	4,165
Warrant derivative liability	2,773	10,345
Private placement option liability	—	7,803
Current portion of lease liabilities	—	825
Liabilities held for sale	—	672
Total current liabilities	6,712	24,701
Long-term lease liabilities	—	344
Total liabilities	6,712	25,045
Commitments and contingencies		
Redeemable Preferred stock: $0.01 par value; 10,000,000 shares authorized		
Series 1 redeemable convertible preferred stock, $0.01 par value, 1,517,500 shares authorized at December 31, 2021 and December 31, 2020, 452,000 shares issued and outstanding at December 31, 2021 and December 31, 2020	18,036	18,036
Stockholders' equity (deficit):		
Common stock, $0.01 par value; 80,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; 8,497,025 shares issued and 8,429,279 shares outstanding at December 31, 2021; 8,385,650 shares issued and 8,317,904 shares outstanding at December 31, 2020	85	84
Treasury stock: 67,746 shares held at December 31, 2021 and December 31, 2020	(5,056)	(5,056)
Additional paid-in capital	580,156	543,561
Accumulated other comprehensive loss	(338)	(339)
Accumulated deficit	(550,452)	(540,747)
Total stockholders' equity (deficit)	24,395	(2,497)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	$ 49,143	$ 40,584

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

Bellicum Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Revenues		
Supply agreement	$ 700	$ 0
License revenue	5,500	500
Total revenues	6,200	500
Operating expenses		
Research and development	23,578	39,052
General and administrative	7,010	15,531
Total operating expenses	30,588	54,583
Other operating income (expense)		
Impairment of property and equipment	—	(1,265)
(Loss) Gain on dispositions, net	(478)	3,656
Total other operating income (expense)	(478)	2,391
Loss from operations	(24,866)	(51,692)
Other income (expense):		
Interest income	32	387
Interest expense	(4)	(2,659)
Change in fair value of warrant and private placement option liabilities	15,126	46,130
Gain on extinguishment of debt	—	112
Other income	7	—
Total other income	15,161	43,970
Net loss	$ (9,705)	$ (7,722)
Net loss per common share attributable to common shareholders, basic and diluted	$ (0.84)	$ (1.34)
Weighted-average shares outstanding-basic and diluted	11,504,294	5,760,159
Net loss	$ (9,705)	$ (7,722)
Other comprehensive income (loss):		
Foreign currency translation adjustment	1	(12)
Comprehensive loss	$ (9,704)	$ (7,734)

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

Bellicum Pharmaceuticals, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity
(amounts in thousands, except share data)

	Series 1 Preferred		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2019	538,000	$ 21,468	5,076,593	$ 507	(67,746)	$ (5,056)	$ 511,684	$ (533,025)	$ (327)	$ (26,217)
Share-based compensation	—	—	—	—	—	—	5,031	—	—	5,031
1-for-10 Reverse Stock Split	—	—	—	(457)	—	—	457	—	—	—
Issuance of common stock - Employee Stock Purchase Plan	—	—	14,975	—	—	—	78	—	—	78
Issuance of common stock upon vesting of restricted stock units	—	—	1,406	—	—	—	—	—	—	—
Issuance of common stock and pre-funded warrants exercise, net of issuance costs	—	—	2,432,676	25	—	—	22,888	—	—	22,913
Conversion of redeemable convertible preferred stock into common stock	(86,000)	(3,432)	860,000	9	—	—	3,423	—	—	3,432
Comprehensive loss	—	—	—	—	—	—	—	(7,722)	(12)	(7,734)
Balance, December 31, 2020	452,000	$ 18,036	8,385,650	$ 84	(67,746)	$ (5,056)	$ 543,561	$ (540,747)	$ (339)	$ (2,497)
Share-based compensation	—	—	—	—	—	—	3,439	—	—	3,439
Issuance of common stock upon vesting of restricted stock units	—	—	111,375	1	—	—	(1)	—	—	—
Issuance of pre-funded warrants, net of issuance costs	—	—	—	—	—	—	32,908	—	—	32,908
Extinguishment of private option liability	—	—	—	—	—	—	249	—	—	249
Comprehensive loss	—	—	—	—	—	—	—	(9,705)	1	(9,704)
Balance, December 31, 2021	452,000	$ 18,036	8,497,025	$ 85	(67,746)	$ (5,056)	$ 580,156	$ (550,452)	$ (338)	$ 24,395

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

Bellicum Pharmaceuticals Inc.
Consolidated Statements of Cash Flows
(in thousands)

	December 31, 2021	December 31, 2020
Cash flows from operating activities:		
Net loss	$ (9,705)	$ (7,722)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	3,439	5,031
Depreciation and amortization expense	105	1,472
Change in fair value of warrant and private placement derivative liabilities	(15,126)	(46,130)
(Gain) loss on dispositions, net	478	(3,656)
Amortization of right-of-use assets	33	402
Accretion of lease liability	23	414
Impairment of property and equipment	—	1,265
Amortization of deferred issuance costs	—	550
Gain on debt extinguishment	—	(112)
Changes in operating assets and liabilities:		
Accounts receivable, interest and other receivables	170	301
Prepaid expenses and other assets	(462)	563
Accounts payable	(801)	(1,917)
Accrued liabilities and other	(1,260)	(7,111)
Net cash used in operating activities	(23,106)	(56,650)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	900	14,705
Purchases of property and equipment	(7)	(625)
Cash provided by investing activities	893	14,080
Cash flows from financing activities:		
Payment on debt	—	(37,155)
Proceeds from exercise of stock options	—	12
Proceeds from issuance of stock from employee stock purchase plan	—	78
Proceeds from issuance of pre-funded warrants, net	32,908	22,901
Payment on financing lease obligations	(35)	(74)
Net cash provided by (used in) financing activities	32,873	(14,238)
Effect of exchange rate changes on cash	1	(12)
Net change in cash, cash equivalents and restricted cash	10,661	(56,820)
Cash, cash equivalents and restricted cash at beginning of period	36,996	93,816
Cash, cash equivalents and restricted cash at end of period	$ 47,657	$ 36,996
Supplemental cash flow information:		
Cash paid during the period for interest	$ —	$ 2,340
Non-cash investing and financing activities:		
Conversion of redeemable preferred stock into common stock	$ —	$ 3,432
Reclassification of property and equipment, net to assets held for sale	$ —	$ 2,300
Leasehold improvements paid by landlord	$ —	$ 113

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

NOTE 1 - ORGANIZATION, BASIS OF PRESENTATION, AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Bellicum Pharmaceuticals, Inc. ("Bellicum") is a clinical stage biopharmaceutical company focused on discovering and developing novel cellular immunotherapies for various forms of cancer. Bellicum is devoting substantially all of its present efforts to developing next-generation CAR-T product candidates in cellular immunotherapy.

Bellicum has two wholly-owned subsidiaries, Bellicum Pharma Limited, a private limited company organized under the laws of the United Kingdom, and Bellicum Pharma GmbH, a private limited liability company organized under German law. Both were formed for the purpose of developing product candidates in Europe. Bellicum, Bellicum Pharma Limited and Bellicum Pharma GmbH are collectively referred to herein as the "Company." All intercompany balances and transactions among the consolidated entities have been eliminated in consolidation.

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company's chief operating decision maker is its Chief Executive Officer who manages operations and reviews the financial information as a single operating segment for purposes of allocating resources and evaluating its financial performance.

Reverse Stock Split

On February 5, 2020, the Company filed a Certificate of Amendment of the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to (i) effect a reverse stock split of all issued and outstanding shares of the Company's common stock at a ratio of 1-for-10 and (ii) reduce the number of authorized shares of the Company's common stock from 200,000,000 to 40,000,000. The accompanying consolidated financial statements and notes to the consolidated financial statements gives retroactive effect to the reverse stock split for all periods presented.

On June 15, 2020, the Company filed with the Secretary of State of the State of Delaware a Second Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to increase the authorized number of shares of the Company's common stock from 40,000,000 shares to 80,000,000 shares.

Basis of Presentation

The accompanying financial statements have been prepared in conformity with the authoritative U.S. generally accepted accounting principles ("GAAP").

The accompanying financial statements have been prepared on a basis that assumes that the Company will continue as a going concern, and do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of the Company's liabilities and commitments in the normal course of business and does not include any adjustments to reflect the possible future effects of the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company has experienced net losses since its inception and if the Company does not successfully obtain regulatory approval and commercialize any of its product candidates, the Company will not be able to achieve profitability. As of December 31, 2021, the Company has an accumulated deficit of $550.5 million.

The Company is subject to risks common to companies in the biotechnology industry and the future success of the Company is dependent on its ability to successfully complete the development of, and obtain regulatory approval for, its product candidates, manage the growth of the organization, obtain additional financing necessary in order to develop, launch and commercialize its product candidates, and compete successfully with other companies in its industry.

The Company believes that its current capital resources, which consist of cash and cash equivalents, are sufficient to fund operations through at least the next twelve months from the date the accompanying financial statements are issued based on the expected cash burn rate. The Company may be required to raise additional capital to fund future operations through the sale of additional equity, incurrence of debt, the entry into licensing or collaboration agreements with partners, grants or other sources of financing. Sufficient funds may not be available to the Company at all or on attractive terms when needed from equity or debt financings. If the Company is unable to obtain additional funding from these or other sources when needed, or to the extent needed, it may be necessary to

significantly reduce its controllable and variable expenditures and current rate of spending through reductions in staff and delaying, scaling back, or suspending certain research and development, sales and marketing programs and other operational goals.

Use of Estimates

The preparation of the financial statements in accordance with GAAP requires management to make certain estimates and judgments that affect the reported amounts of assets, liabilities, revenue recognition, and expenses. Actual results could differ materially from those estimates.

Revenue Recognition

The Company's sources of revenue in 2021 were from its supply agreement with Takeda Development Center Americas, Inc. ("Takeda") and from its licensing agreements with The University of Texas MD Anderson Cancer Center ("MD Anderson"). The Company has generated revenue from its licensing agreements since 2019. Prior to 2019, the Company's only source of revenue was from grants.

Supply of Product

The promised product in the supply agreement with Takeda consists of rimiducid including any components, drug substance, raw materials and/or excipients to be supplied by the Company. Revenue is generally recognized upon the transfer of control of promised goods to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods.

On May 4, 2021, the Company entered a multi-year supply agreement with Takeda. The Company will supply Takeda with rimiducid for potential use in clinical trials of TAK-007 (CD19 CAR-NK cell therapy). The Company generated revenue of $0.7 million in the second quarter of 2021, with the possibility of additional revenue from future sales.

Licenses of Intellectual Property

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, revenue is recognized from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company uses judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over a period of time or at a point in time. If over a period of time, the Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

On January 22, 2019, the Company entered into a licensing and commercialization agreement with MD Anderson (the "2019 MD Anderson License Agreement"). Under the 2019 MD Anderson License Agreement, the Company granted MD Anderson non-exclusive rights in certain Caspase-9 and related technologies and use of a small molecule known as rimiducid in a certain cell therapy program. During the fourth quarter of 2019, and under the terms of the 2019 MD Anderson License Agreement, MD Anderson exercised an option to grant a non-exclusive sublicense of the rights licensed by the Company to MD Anderson. MD Anderson, as a result of this exercise, granted a sublicense that entitled the Company to receive as consideration an upfront license fee as well as additional future annual maintenance fees, milestone payments related to the achievement of pre-specified development, regulatory, and commercialization events, and royalties on net sales of licensed products.

On August 31, 2021, the Company entered into a second licensing and commercialization agreement with MD Anderson (the "2021 MD Anderson Option and License Agreement"). Under the 2021 MD Anderson Option and License Agreement, MD Anderson has certain rights to the use of CaspaCIDe and rimiducid in product candidates nominated under the agreement, and receives options to non-exclusive licenses to the technology in these candidates. These options were evaluated and were not determined to be material rights. Upon sublicense of the product candidates nominated under the agreement, or upon exercise of an option and sublicense of a product candidate to a third party, the Company is entitled to a sublicense execution fee, a percentage of certain consideration received by MD Anderson for the sublicense, an annual maintenance fee, and a percentage royalty on net sales of licensed products. During the third quarter of 2021, the Company received an upfront payment of $5.0 million, which was recognized as revenue upon execution of the agreement, and granted licenses for two nominated programs.

Milestone Payments

At the inception of each arrangement that includes developmental, regulatory or commercial milestone payments, the Company evaluates whether achieving the milestones is considered probable and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within the Company's control, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized from the satisfaction of performance obligations when such obligations have been fulfilled.

Royalty Revenues

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, no royalties have been received.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all short-term, highly liquid investments with a maturity of three months or less from the date of purchase and that can be liquidated without prior notice or penalty, to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same such amounts shown in the statements of cash flows.

(in thousands)	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 46,156	$ 35,495
Restricted cash	1,501	1,501
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 47,657	$ 36,996

In connection with the closing of the Asset Purchase Agreement with M.D. Anderson on April 14, 2020, $1.5 million of the cash proceeds received are subject to certain escrow provisions and recorded as restricted cash. The funds are required to be held until any claims against the escrow are resolved.

Disposition of Assets and Liabilities Held for Sale and Held for Use

In the fourth quarter of 2020, in connection with the Company's restructuring plan, Management elected to seek an exit to its leased manufacturing facility in Houston, Texas. As a result of this decision, the Company reclassified the assets and liabilities associated with the leased facility as held for sale. The reclassified assets and liabilities included a right-of-use asset of $0.5 million, property and equipment of $2.3 million and the related lease liability of $0.7 million. Based on the cost to exit the lease and the net realizable value of the related assets, the Company recognized an impairment charge of $1.3 million in the fourth quarter of 2020.

The disposal of the assets and liabilities associated with the Houston facility was completed on February 26, 2021. Under the terms of the agreement, a third party assumed the lease for the facility. In addition, the third party paid $1.1 million to the Company for substantially all of the property and equipment associated with the location. The consideration included $0.9 million in cash and an unsecured promissory note for $0.2 million.

On March 15, 2021, the Company entered an agreement to terminate its sub-lease of the South San Francisco office space contingent upon consent of the prime lessor. Under the terms of the agreement, the company agreed to pay a lease termination fee of $0.9 million while the security deposit of $0.2 million was returned to the Company in June 2021. The decision to exit this lease reflects the ability of the Company to carry on its administrative function remotely. On March 26, 2021, the Company met all of the conditions of the agreement and disposed of substantially all of the assets and liabilities associated with the lease including the right-of-use asset of $0.6 million, leased equipment with a net book value less than $0.1 million, and the related lease liability of $1.0 million. The Company recognized a loss on termination of $0.5 million during the first quarter of 2021.

Property and Equipment

Furniture, equipment and software are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets, which range from 3 to 5 years. Leasehold improvements are amortized over the shorter of the estimated useful life or the remaining lease term.

Property and equipment consisted of the following:

(in thousands, except useful lives)	Estimated Useful Lives	December 31, 2021	December 31, 2020
Leasehold improvements	5 Years	$ —	$ 167
Lab equipment	5 Years	530	530
Manufacturing equipment	5 Years	138	138
Computer and office equipment	3 to 5 Years	841	834
Software	3 Years	94	94
Total		1,603	1,763
Less: accumulated depreciation		(1,591)	(1,574)
Property and equipment, net		$ 12	$ 189

During the years ended December 31, 2021 and 2020, the Company recorded $0.1 million and $1.5 million of depreciation expense, respectively.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in business conditions indicate that their carrying value may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other liabilities consist of the following:

	December 31, 2021	December 31, 2020
Accrued payroll	$ 320	$ 1,071
Accrued patient treatment costs	2,086	899
Accrued clinical research costs	479	1,562
Accrued manufacturing costs	328	41
Accrued professional services	305	279
Accrued other	331	313
Total accrued expenses and other current liabilities	$ 3,849	$ 4,165

Certain prior year amounts have been reclassified to conform to the 2021 presentation. Expenses related to clinical studies totaling $1.5 million were reclassified from Accrued Other to Accrued Clinical Research Costs. Another $0.1 million for expenses related to drug manufacture and professional consulting services were reclassified from Accrued Other to Accrued Manufacturing Costs and Accrued Professional Services.

Warrant Derivatives

In an underwritten public offering (the “2019 Offering”), the Company issued Series 1 Redeemable Convertible Non-Voting Preferred Stock (the “Series 1 Preferred Stock”) and warrants (the “2019 Public Warrants”) to purchase its common stock. These 2019 Public Warrants are classified as liabilities in the accompanying consolidated balance sheets, because the public warrants embody a conditional or unconditional obligation to repurchase the Company’s shares. The Company accounted for these warrants at fair value on the date of issuance and they are subject to re-measurement to fair value at each balance sheet date. Any change in fair value is recognized as a component of other income (expense) on the accompanying consolidated statements of operations and comprehensive loss. The Company estimates the fair value of these liabilities using the Black-Scholes valuation technique, which utilizes assumptions including (i) the fair value of the underlying stock at the valuation measurement date, (ii) volatility of the price of the underlying stock, (iii) the expected term, and (iv) risk-free interest rates. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants or a change in control, as defined. The warrants are freely exercisable at any time from the issuance date until the expiration date, provided exercise does not cause a warrant holder to exceed a pre-determined beneficial ownership limit. See Note 5 - Public Offering and Private Placement for discussions of the 2019 Public Warrants.

In November 2020 and December 2021, the Company issued prefunded warrants and accompanying warrants (the "2020 Pre-funded Warrants" and "2020 Common Warrants", the "2021 Pre-funded Warrants" and "2021 Common Warrants", respectively). These pre-funded warrants and common warrants are classified as equity. The pre-funded warrants and common warrants neither embody a conditional or unconditional obligation, nor are they indexed to an obligation, to repurchase the Company's shares by transferring assets. Furthermore, the monetary value of the pre-funded warrants and accompanying warrants, at inception, is not solely or predominately based on (a) a fixed monetary amount, (b) variations in something other than the fair value of the Company's shares, or (c) variations inversely related to the fair value of the Company's own shares. Therefore, the pre-funded warrants and common warrants do not meet the criteria requiring liability classification. See Note 5 - Public Offering and Private Placement for discussions of the 2020 Pre-funded and Common Warrants and 2021 Pre-funded and Common Warrants.

Private Placement Option

Besides the 2019 Offering, the Company completed a private placement and entered into the 2019 Securities Purchase Agreement that contained a call option on preferred shares that are puttable outside the control of the Company. Prior to the fourth quarter of 2021, the Company recorded the option as a liability and measured the option at fair value. The Company re-measured the option to fair value at each balance sheet date and recorded changes in fair value in other income (expense) in the accompanying consolidated statement of operations and comprehensive loss at each reporting period. Offering expenses arising from the issuance of the private placement option were expensed as incurred.

The Company estimated the fair value of these liabilities using a binomial lattice model, which utilized assumptions including (i) the fair value of the underlying stock at the valuation measurement date, (ii) volatility of the price of the underlying stock, (iii) the expected term, and (iv) risk-free interest rates.

In 2021, the Company entered into the 2021 Securities Purchase Agreement, pursuant to which certain of the purchasers irrevocably waived the right to cause the Company to conduct the "First Closing" and "Second Closing" under the private placement option contained in the 2019 Securities Purchase Agreement (each term as defined in the 2019 Securities Purchase Agreement), which releases the Company of potential obligations. The Company has therefore derecognized the option liability at its balance sheet date ended on December 31, 2021.

Preferred Stock

Preferred shares issued by the Company that are subject to mandatory redemption are classified as liability instruments in the accompanying consolidated balance sheets and are measured at fair value at the date of issuance. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified within mezzanine equity in the accompanying consolidated balance sheets. At all other times, preferred shares are classified within stockholders' deficit.

Operating Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, upon lease commencement, the Company records a lease liability which represents the Company's obligation to make lease payments arising from the lease, and a corresponding right-of-use ("ROU") asset which represents the Company's right to use an underlying asset during the lease term.

Operating leases are recognized as ROU assets and operating lease liabilities on the balance sheet at the commencement date based on the present value of the future minimum lease payments over the lease term calculated using the Company's incremental borrowing rate applicable to the underlying asset unless the implicit rate is readily determinable. Any lease incentives received are deferred and recorded as a reduction of the ROU asset and amortized over the term of the lease. Rent expense, comprised of amortization of the ROU asset and the implicit interest accreted on the operating lease liability, is recognized on a straight-line basis over the lease term. The Company determines the lease term as the noncancellable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. Leases with a term of 12 months or less are not recognized on the balance sheets.

Fair Value of Financial Instruments

Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a fair value hierarchy has been established that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

These inputs are classified into the following hierarchy:

Level 1 Inputs - quoted prices (unadjusted) in active markets for identical assets that the reporting entity has the ability to access at the measurement date;

Level 2 Inputs - inputs other than quoted prices included within Level 1 that are observable for the asset, either directly or indirectly; and

Level 3 Inputs - unobservable inputs for the assets.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company believes the recorded values of its financial instruments, including cash and cash equivalents, accounts payable, accrued liabilities, and debt approximate their fair values due to the short-term nature of these instruments.

Financial Instruments and Credit Risks

Financial instruments that potentially subject the Company to credit risk include cash and cash equivalents and accounts receivable. Cash is deposited in demand accounts in federally insured domestic institutions to minimize risk. Insurance is provided through the Federal Deposit Insurance Corporation and Security Investor Protection Corporation. Although the balances in these accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

Equity Issuance Costs

Equity issuance costs represent costs paid to third parties in order to obtain equity financing. These costs have been netted against the proceeds of the equity issuances.

Licenses and Patents

Licenses and patent costs for technologies that are utilized in research and development and have no alternative future use are expensed as incurred. Costs related to the license of patents from third parties and internally developed patents are classified as research and development expenses. Legal costs related to patent applications and maintenance are classified as general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for research and development employees and consultants, facilities expenses, overhead expenses, cost of laboratory supplies, manufacturing expenses, fees paid to third parties and other outside expenses.

Research and development costs are expensed as incurred. Clinical trial and other development costs incurred by third parties are expensed as the contracted work is performed. The Company accrues for costs incurred as the services are being provided by monitoring the status of the clinical trial or project and the invoices received from its external service providers. The Company's estimates depend on the timeliness and accuracy of the data provided by the vendors regarding the status of each project and total project spending. The Company adjusts its accrual as actual costs become known.

Collaboration Agreements

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as a deduction to the research and development expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, the Company also recognizes, as research and development expenses in the period when its collaborator incurs development expenses, the portion of the collaborator's development expenses that the Company is obligated to reimburse.

Contract Manufacturing Services

Contract manufacturing services are expensed as incurred. Prepaid expenses are capitalized and amortized as services are performed.

Share-Based Compensation

The Company accounts for share-based compensation based on the measurement and recognition of compensation expense for all share-based payment awards made to employees, directors and consultants to be recognized in the financial statements, based on their fair value.

The Company calculates the fair value of stock options on the date of grant using the Black-Scholes pricing model, which requires a number of estimates, including the expected life of awards, interest rates, stock volatility and other assumptions. Restricted stock is measured based on the fair market value of the underlying stock on the date of grant. If the awards are classified as liability awards, the fair value is remeasured at each reporting date and the compensation expense is adjusted accordingly. Additionally, the Company applies a forfeiture rate to estimate the number of grants that will ultimately vest, as applicable, and adjusts the expense as these awards vest. All of the Company's current equity awards are service based awards and the share-based compensation cost is being recognized over the requisite service period of the awards on a straight-line basis.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. This method also requires the recognition of future tax benefits such as net operating loss and tax credit carry forwards, to the extent that realization of such benefits is more likely than not. A valuation allowance is recorded when the realization of future tax benefits is uncertain. The Company records a valuation allowance for the full amount of deferred tax assets, which would otherwise be recorded for tax benefits relating to the operating loss and tax credit carryforwards, as realization of such deferred tax assets cannot be determined to be more likely than not.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the statement of operations in the period that includes the enactment date.

As of December 31, 2021, the Company had recorded a full valuation allowance on its net U.S. and foreign deferred tax assets because the Company expects that it is more likely than not that its deferred tax assets will not be realized in the foreseeable future. Should the actual amounts differ from our estimates, the amount of the valuation allowance could be materially impacted.

The Company accounts for uncertain tax positions in accordance with the provisions of the Accounting Standards Codification (ASC) 740, *Income Taxes*. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2021 and 2020, the Company had no uncertain tax positions and no interest or penalties have been charged for the years ended December 31, 2021 and 2020. The Company is subject to routine audits by taxing jurisdictions; however, there are currently no audits for any tax periods in progress. The tax years 2005 through 2021 remain open to examination by the U.S. Internal Revenue Service.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period, from transactions, and other events and circumstances from non-owner sources. Components of other comprehensive loss includes, among other items, unrealized gains and losses on the changes in fair value of investments and unrealized gains and losses on the change in foreign currency exchange rates. These components are added, net of their related tax effect, to the reported net loss to arrive at comprehensive loss.

Net Loss and Net Loss per Share of Common Stock Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period without consideration for common stock equivalents. Diluted earnings per share is based on the more dilutive method between the two-class method and the treasury stock method and includes the effect from potential issuance of ordinary shares, such as shares issuable pursuant to the conversion of preferred stock to common stock, exercise of warrants to purchase common stock, exercise of stock options, and vesting of restricted stock units. For periods of net loss, diluted net loss per share is calculated similarly to basic net loss per share.

The following outstanding shares of common stock equivalents were excluded from the computations of diluted earnings per share (if in a net income position) of common stock attributable to common stockholders for the periods presented as the effect of including such securities would be anti-dilutive.

	December 31, 2021	December 31, 2020
Anti-dilutive common stock equivalents:	Number of Shares	
Redeemable convertible series 1 preferred stock	4,520,000	4,520,000
Warrants to purchase common stock	5,750,000	11,616,080
Private placement option	—	9,675,000
Options to purchase common stock	2,140,618	1,510,968
Unvested shares of restricted stock units	137,504	129,861
Total anti-dilutive common stock equivalents	12,548,122	27,451,909

New Accounting Requirements and Disclosures

Financial Instruments – Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement of all expected credit losses for financial assets including trade receivables held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. ASU No. 2016-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020 with no material effect on its financial statements. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments - Credit Losses. This ASU does not change the core principle of the guidance in ASU 2016-13, instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses guidance. The FASB also subsequently issued ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Derivatives and Hedging (Topic 815), and Financial Instruments (Topic 842), which did not change the core principle of the guidance in ASU 2016-13 but clarified that expected recoveries of amounts previously written off and expected to be written off should be included in the valuation account and should not exceed amounts previously written off and expected to be written off. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019 for public business entities, excluding smaller reporting companies. Early adoption is permitted. As a smaller reporting company, the guidance will be effective for the Company during the first quarter of 2023. The Company is in the process of assessing the impact adoption will have on its consolidated financial statements.

Investments

In January 2020, the FASB issued Accounting Standards Update No. 2020-01, *Investments—Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)—Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the Emerging Issues Task Force)*, which clarifies the interaction of the accounting for equity securities, investments accounted for under the equity method, and certain forward contracts and purchased options. This update is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years, and early adoption is permitted. The Company adopted the standard effective January 1, 2021 with no impact on its consolidated financial statements.

Convertible Instruments

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*, which reduces the number of accounting models for convertible debt instruments and convertible preferred stock. In addition, the update amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. Furthermore, this update improves the related EPS guidance. This update is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years, and early adoption is permitted. The Company adopted the standard effective January 1, 2021 with no impact on its consolidated financial statements.

NOTE 2 - FAIR VALUE OF MEASUREMENTS AND INVESTMENT SECURITIES

Investment Securities

The following tables present the Company's investment securities (including those classified on the Company's balance sheet as cash equivalents) that are measured at fair value on a recurring basis as of December 31, 2021 and 2020:

	Fair Value at December 31, 2021			Fair Value at December 31, 2020		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Cash Equivalents:						
Money market funds and treasury bills	$ 42,487	$ —	$ —	$ 27,463	$ —	$ —
Total Cash Equivalents	$ 42,487	$ —	$ —	$ 27,463	$ —	$ —

Additionally, the $1.5 million of restricted cash on the Company's balance sheet is held in a money market fund as of December 31, 2021.

Money market funds and U.S. Treasury bills are valued based on various observable inputs such as benchmark yields, reported trades, broker/dealer quotes, benchmark securities and bids.

Warrant Derivative Liability and Private Placement Option Liability

The Company's financial liabilities recorded at fair value on a recurring basis include the fair values of the warrant derivative liability and the private placement option liability prior to its derecognition in December 2021. Inputs used to determine estimated fair value (Level 3) of the warrants include the fair value of the underlying stock relative to the warrant exercise price at the valuation measurement date, volatility of the price of the underlying stock, the expected term of the warrants, and risk-free interest rates.

The fair values of the warrant derivative liability and the private placement option liability, prior to its derecognition in December 2021, are classified as current liabilities in the accompanying consolidated balance sheets. These liabilities will be shown as current liabilities on the balance sheet when it is deemed more probable than not by management to be exercised within one year. On December 4, 2021, the Company entered into the 2021 Securities Purchase Agreement, pursuant to which certain of the investors irrevocably waived the right to cause the Company to conduct the "First Closing" and "Second Closing" under the private placement option contained in the 2019 Securities Purchase Agreement (each term as defined in the 2019 Securities Purchase Agreement). The Company derecognized the private placement option liability and recorded a gain on change in the fair value for the year ended December 31, 2021 of $2.8 million in the accompanying statements of operations and comprehensive loss.

The fair value of the warrants has been estimated with the following weighted-average assumptions, including the most sensitive input, volatility:

	December 31, 2021	December 31, 2020
Risk-free interest rate	1.22 %	0.46 %
Volatility	94 %	90 %
Expected life (years)	4.64	5.64

The following table provides the warrant derivative and private placement option liabilities reported at fair value and measured on a recurring basis:

	Fair Value at December 31, 2021			Fair Value at December 31, 2020		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Warrant derivative liability	$ —	$ —	$ 2,773	$ —	$ —	$ 10,345
Private placement option liability	—	—	—	—	—	7,803
Total fair value	$ —	$ —	$ 2,773	$ —	$ —	$ 18,148

The ending balance of the Level 3 financial instruments presented above represents the Company's best estimate of valuation and may not be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instruments.

NOTE 3 - LEASES

The Company entered into a lease agreement for office and laboratory space in Houston, Texas commencing in July 2020 and expiring in 2023. The Company recorded ROU assets of $0.5 million and a corresponding lease liability of $0.6 million upon lease commencement. In October 2020, in connection with the Company's restructuring plan, Management elected to seek an exit to its leased office and laboratory space in Houston, Texas. As a result of this decision, the Company reclassified the assets and liabilities associated with the leased facility as held for sale. The reclassified assets included a right-of-use asset of $0.5 million, property and equipment of $2.3 million, and related lease liability of $0.7 million. Based on the cost to exit the lease and the net realizable value of the related assets, the Company recognized an impairment charge of $1.3 million in 2020. The disposal of the assets and liabilities associated with the facility was completed on February 26, 2021. Under the terms of the agreement a third party assumed the lease for the facility. In addition, the third party paid $1.1 million to the Company for substantially all of the property, and equipment associated with the location. The consideration included $0.9 million in cash and an unsecured promissory note for $0.2 million.

On March 15, 2021, the Company entered an agreement to terminate its sub-lease of the South San Francisco office space contingent upon consent of the prime lessor. Under the terms of the agreement, the company agreed to pay a lease termination fee of $0.9 million while the security deposit of $0.2 million was returned to the Company. On March 26, 2021, the Company met all of the conditions of the agreement and disposed of substantially all of the assets and liabilities associated with the lease including the right-of-use asset of $0.6 million, leased equipment with net book value less than $0.1 million, and the related lease liability of $1.0 million. The Company recognized a loss on termination of $0.5 million during the year ended December 31, 2021.

Components of lease cost are as follows:

(in thousands)	Year Ended December 31, 2021	Year Ended December 31, 2020
Finance lease cost:		
Amortization of leased assets	$ 16	$ 74
Interest on lease liabilities	5	21
Operating lease cost	56	814
Short-term lease cost	53	582
Total lease cost	$ 130	$ 1,491
Weighted-average remaining lease term:		
Operating leases	0.0 years	1.7 years
Finance leases	0.0 years	1.4 years
Weighted-average discount rate:		
Operating leases	— %	11.47 %
Finance leases	— %	13.05 %

Supplemental cash flow information and non-cash activity related to the Company's operating and finance leases are as follows:

(in thousands)	Year Ended December 31, 2021	Year Ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 71	$ 950
Operating cash flows from finance leases	5	21
Financing cash flows from finance leases	35	74

NOTE 4 - DEBT

Oxford Loan

On December 21, 2017 (the "Oxford Closing Date"), the Company entered into a loan and security agreement (the "Oxford Loan Agreement") with Oxford Finance LLC, pursuant to which the Company borrowed $35.0 million in a single term loan (the "Oxford Loan"). On the Oxford Closing Date, the Company used approximately $32.9 million of the proceeds from the Oxford Loan to repay its indebtedness to a previous lender.

The Company paid expenses related to the Oxford Loan Agreement of $0.1 million, which, along with the final facility charge of $3.0 million, were recorded as deferred issuance costs, which offset long-term debt on the Company's consolidated balance sheet. The deferred issuance costs were being amortized over the term of the loan as interest expense using the effective interest method. During the year ended December 31, 2020, interest expense included $0.6 million of amortized deferred issuance costs.

During November 2020, the Company entered into an agreement for the early settlement of all debt obligations under the Oxford Loan Agreement. During the same month, the Company remitted payment of $27.4 million, which included full repayment of the outstanding principal balance, the Oxford Final Payment Fee, and accrued interest. As of December 31, 2020, the Company recorded a gain on extinguishment of $0.1 million in the accompanying statements of operations and comprehensive loss.

NOTE 5 - PUBLIC OFFERING AND PRIVATE PLACEMENT

December 2021 Private Placement

On December 4, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Securities Purchase Agreement") with certain institutional investors (the "Purchasers"), pursuant to which the Company agreed to issue to the Purchasers 2021 pre-funded warrants to purchase an aggregate of 20,559,210 shares of its common stock and accompanying 2021 common warrants to purchase an aggregate of 2,055,920 shares of common stock. Each pre-funded warrant to purchase one share of common stock will be sold together with a warrant to purchase one-tenth of one share of common stock at a combined unit price of $1.7024. The pre-funded warrants will be immediately exercisable at an exercise price of $0.0001 per share of common stock. The accompanying common warrants will be immediately exercisable at an exercise price of $1.69 per share of common stock and will expire seven years from the date of issuance.

The gross proceeds to the Company from the private placement were approximately $35.0 million before deducting placement agent commissions and offering expenses payable by the Company, excluding any proceeds that may be received upon exercise of the accompanying warrants.

In addition, pursuant to the 2021 Securities Purchase Agreement, certain of the Purchasers irrevocably waived the right to cause the Company to conduct the "First Closing" and "Second Closing" under the 2019 Securities Purchase Agreement (each term as defined in the 2019 Securities Purchase Agreement), which releases the Company of potential cash or equity obligations. The representations, warranties and covenants contained in the 2021 Securities Purchase Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement and may be subject to limitations agreed upon by the contracting parties.

November 2020 Underwritten Offering

On November 2, 2020, the Company closed an underwritten offering of 1,040,000 shares of its common stock, 2020 pre-funded warrants to purchase 3,109,378 shares of its common stock, and accompanying 2020 common warrants to purchase up to an aggregate of 4,149,378 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $6.025 and $6.024 for each pre-funded warrant. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of common stock. The common warrants were immediately exercisable at an exercise price of $6.50 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The gross proceeds to the Company were approximately $25.0 million before deducting underwriting discounts and commissions and other offering expenses.

August 2019 Public Offering

On August 16, 2019, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Jefferies LLC and Wells Fargo Securities, LLC, as representatives of the several underwriters named therein (the "Underwriters"), relating to an underwritten public offering (the "2019 Offering") of 575,000 shares of the Series 1 Redeemable Convertible Non-Voting Preferred Stock of the Company (the "Series 1 Preferred Stock") and warrants (the "2019 Public Warrants") to purchase up to 5,750,000 shares of its common stock. Each share of Series 1 Preferred Stock was sold together with a warrant to purchase 10 shares of common stock at a combined price to the public of $100.00. Under certain circumstances, each warrant to purchase 10 shares of common stock will be exercisable, at the irrevocable election of the holder, for one share of Series 1 Preferred Stock. The offering closed on August 21, 2019, and the net proceeds to the Company from the Offering was approximately $53.8 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company, and excluding any proceeds that the Company may receive upon exercise of the Public Warrants.

All of the 2019 Public Warrants sold in the 2019 Offering have an exercise price of $13.00 per share of common stock or, in certain circumstances, for $130.00 per share of Series 1 Preferred Stock, subject to proportional adjustments in the event of stock splits or combinations or similar events. The 2019 Public Warrants were immediately exercisable upon issuance, provided that the holder is prohibited, subject to certain exceptions, from exercising a warrant for shares of common stock to the extent that immediately prior to or after giving effect to such exercise, the holder, together with its affiliates and other attribution parties, would own more than 9.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 19.99% upon 61 days' notice to the Company. The Public Warrants will expire on August 21, 2026, unless exercised prior to that date

The following table reflects the fair value roll forward reconciliation of the 2019 Public Warrants liabilities for the period ended December 31, 2021:

(in thousands)	Warrant Derivative Liability
Balance, December 31, 2020	$ 10,345
Change in fair value	(7,572)
Balance, December 31, 2021	$ 2,773

Private Placement

On August 16, 2019, the Company entered into a securities purchase agreement (the "2019 Securities Purchase Agreement") with certain institutional investors named therein (the "Purchasers"), pursuant to which the Company agreed to issue in a private placement (i) 350,000 shares of its Series 2 Redeemable Convertible Non-Voting Preferred Stock (the "Series 2 Preferred Stock"), at a purchase price of $100.00 per share, and related warrants to purchase up to 2,800,000 shares of common stock at an exercise price of $10.00 per share, and (ii) 250,000 shares of its Series 3 Redeemable Convertible Non-Voting Preferred Stock (the "Series 3 Preferred Stock" and, together with the Series 1 Preferred Stock and Series 2 Preferred Stock, the "Preferred Stock"), at a purchase price of $140.00 per share, and related warrants to purchase up to 875,000 shares of common stock at an exercise price of $14.00 per share. The right of the Purchasers to purchase such securities was waived, effective as of December 4, 2021, pursuant to the 2021 Purchase Agreement.

The Company received $11.2 million in net option fee proceeds, net of offering costs, upon the execution of the 2019 Securities Purchase Agreement. Pursuant to the 2021 Securities Purchase Agreement entered into on December 4, 2021, the Company derecognized the private placement option liability, and the Company is no longer obligated to issue the Series 2 Preferred Stock, Series 3 Preferred Stock, or any associated Private Warrants.

A summary of warrants outstanding and exercisable as of December 31, 2021 is as follows:

	Warrants Outstanding			Warrants Exercisable	
Year Issued	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
		(in years)	(per share)		(per share)
2019	5,750,000	4.64	$ 13.00	5,750,000	$ 13.00
2020	4,149,378	3.84	$ 6.50	4,149,378	$ 6.50
2020[1]	1,716,702	—	$ —	1,716,702	$ —
2021	2,055,920	6.94	$ 1.69	2,055,920	$ 1.69
2021[2]	20,559,210	—	$ —	20,559,210	$ —
	34,231,210			34,231,210	

NOTE 6 - REDEEMABLE CONVERTIBLE PREFERRED STOCK

In August 2019, the Company sold Series 1 Preferred Stock pursuant to the 2019 Offering. The Company has 10,000,000 authorized shares of preferred stock with a par value of $0.01, of which the Company has designated 1,517,500 shares as Series 1 redeemable convertible non-voting preferred stock, 350,000 shares as Series 2 redeemable convertible non-voting preferred stock and 250,000 shares as Series 3 redeemable convertible non-voting preferred stock. There were 452,000 shares of Series 1 Preferred Stock issued and outstanding as of both December 31, 2021 and 2020. There were no shares of Series 2 or 3 Preferred Stock issued or outstanding as of December 31, 2020, and the Series 2 and 3 Preferred Stock were cancelled during 2021 pursuant to the 2021 Securities Purchase Agreement. The Series 1 Preferred Stock was issued together with warrants for a combined purchase price of $100.00 per share of Series 1 Preferred Stock and one warrant to purchase 10 shares of common stock. There were 86,000 shares of Series 1 Preferred Stock converted to common stock as of December 31, 2020, while no shares were converted during 2021.

As of December 31, 2021 and 2020, the Company classified the Series 1 preferred stock within mezzanine equity, as the Series 1 preferred stock is redeemable at the option of the holders upon passage of time, which is outside of the Company's control to prevent.

The Series 1 Preferred Stock is not currently redeemable and is only redeemable upon a fundamental change at a redemption price. The Company does not believe a fundamental change is considered probable until it occurs. Subsequent adjustment of the amount presented within mezzanine equity to its redemption amount is unnecessary if it is not probable that the instrument will become redeemable. As (i) the Series 1 Preferred Stock is only redeemable upon a fundamental change, the occurrence of which is not

[1] *The pre-funded warrants issued on November 2, 2020 do not have an expiration date.*

[2] *The pre-funded warrants issued on December 7, 2021 do not have an expiration date.*

probable, and (ii) the occurrence of Transition Date (defined below) is probable, the Company did not accrete the Series 1 Preferred Stock to its redemption amount.

Optional Conversion

Each share of Preferred Stock is initially convertible into 10 shares of Common Stock. The conversion price at which Preferred Stock may be converted into shares of common stock is subject to adjustment in connection with certain specified events.

Redemption

Until the applicable Transition Date (defined below), at any time on or after the date that is the fifth (5th) anniversary of the initial issue date of the applicable series of preferred stock, all or any portion of the preferred stock is redeemable at the option of the holder at a redemption price of $100.00 per share (for Series 1 Preferred Stock). The "Transition Date" means the first date following August 21, 2021, on which each of the Conditions (as defined below) is met.

The "Conditions" mean: (1) the closing price of the Company's common stock has been equal to or exceeded $25.00 per share for 180 calendar days (for determining if the Conditions are met for the Series 1 Preferred Stock) for 180 calendar days; (2) the 50-day average trading volume of the Company's common stock on the Nasdaq stock market is greater than 50,000 shares; and (3) a Phase 3 or Phase 2 pivotal clinical trial for one of the Company's CAR-T product candidates has been initiated, meaning that at least one clinical trial site has been activated.

Dividends

Shares of Preferred Stock will be entitled to receive dividends equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of common stock.

Liquidation

Until the applicable Transition Date, in the event of a liquidation, dissolution, winding up or deemed liquidation, holders of the Preferred Stock will receive a payment equal to the applicable per share purchase price of their Preferred Stock before any proceeds are distributed to the holders of Common Stock. The liquidation preferences, protective voting provisions and redemption rights of the Preferred Stock will terminate upon the occurrence of certain events.

Voting

Shares of Preferred Stock will generally have no voting rights, except to the extent expressly provided in the Company's certificate of incorporation or as otherwise required by law.

NOTE 7 - SHARE-BASED COMPENSATION PLANS

The Company has five share-based compensation plans, including the 2019 Equity Incentive Plan the ("2019 Plan") which was adopted in June 2019. Each plan authorizes the granting of shares of common stock and/or options to purchase common stock to employees and directors of the Company, as well as non-employee consultants, and allows the holder of the option to purchase common stock at a stated exercise price. The only plan under which the Company may currently grant equity awards is the 2019 Equity Incentive Plan although there remain outstanding awards under the other four plans. Options vest according to the terms of the grant, which may be immediately or based on the passage of time, generally over two to four years, and have a term of up to 10 years. Unexercised stock options terminate on the expiration date of the grant. The Company recognizes the share-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period.

2019 Equity Incentive Plan

The 2019 Plan, is designed to secure and retain the services of the Company's employees and directors. The 2019 Plan is successor to and continuation of the 2014 Equity Incentive Plan, as amended, the ("2014 Plan"), and no additional awards may be issued from the 2014 Plan. Subject to adjustment for certain changes in the Company's capitalization, the aggregate number of shares of common stock that may be issued under the 2019 Plan (the "Share Reserve") will not exceed the sum of (i) 250,000 new shares, plus (ii) an additional 600,000 shares that were approved at the Company's Special Meeting of Stockholders in January 2020, plus (iii) an additional 500,000 shares that were approved at the Company's Annual meeting of Stockholders in June 2020, (iv) an additional 500,000 shares that were approved at the Company's Annual Meeting of Stockholders in June 2021 and plus (v) the Prior Plans' Returning Shares, as defined in the 2019 Plan documents, in an amount not to exceed 600,540 shares, including any stock award granted under the 2014 Plan, 2011 Stock Option Plan, as amended, or 2006 Stock Option Plan, as amended, that were outstanding as of the date the 2019 Plan were approved by the Company's stockholders, as such shares become available from time to time.

The following shares of common stock (the "2019 Plan Returning Shares") will also become available again for issuance under the 2019 Plan: (i) any shares subject to a stock award granted under the 2019 Plan that are not issued because such stock award expires or otherwise terminates without all of the shares covered by such stock award having been issued; (ii) any shares subject to a stock award granted under the 2019 Plan that are not issued because such stock award is settled in cash; and (iii) any shares issued pursuant to a stock award granted under the 2019 Plan that are forfeited back to or repurchased by the Company because of a failure to vest.

The 2019 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, and other stock awards.

At December 31, 2021 and 2020, outstanding awards were comprised of the following:

	December 31, 2021	December 31, 2020
Options	2,074,858	1,425,207
Inducement option awards	65,760	85,761
Restricted stock units	137,004	129,361
Inducement restricted stock units	500	500
Total outstanding awards	2,278,122	1,640,829

Grant Date Fair Value

The valuation of the share-based compensation awards is a significant accounting estimate that requires the use of judgments and assumptions that are likely to have a material impact on the financial statements. The fair value of option grants is determined using the Black-Scholes option-pricing model. Expected volatilities utilized in the model are based on historical volatility of the Company's common stock. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. As the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term is calculated as the midpoint between the weighted-average vesting term and the contractual expiration period also known as the simplified method.

The fair value of the option grants has been estimated, with the following weighted-average assumptions:

	Year Ended	
	December 31, 2021	December 31, 2020
Options granted	1,023,000	1,352,595
Weighted-average exercise price	2.80	7.59
Weighted-average grant date fair value	2.02	5.29
Assumptions:		
Risk-free interest rate	0.92 %	0.82 %
Volatility	90 %	85 %
Expected life (years)	5.63	5.83
Expected dividend yield	—	—

Share-Based Compensation Activity

The following table summarizes the stock option activity for all stock plans during the year ended December 31, 2021 and 2020 as follows:

Options	Outstanding Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term *(in years)*	Aggregate Intrinsic Value *(in thousands)*
Balance at December 31, 2019	567,842	$ 76.25	7.82	$ 12
Granted	1,352,595	$ 7.59		
Exercised	—			
Forfeited	(409,469)	$ 29.86		
Balance at December 31, 2020	1,510,968	$ 27.36	8.19	$ 379
Granted	1,023,000	$ 2.80		
Exercised	—			
Forfeited	(393,350)	$ 30.66		
Balance at December 31, 2021	2,140,618	$ 15.01	8.48	$ —
Exercisable at December 31, 2021	718,123	$ 36.42	6.98	$ —

There were no options exercised or cash received for the year ended December 31, 2021; the Company received cash of less than $0.1 million upon option exercises for year ended December 31, 2020.

The following table summarizes the options outstanding and exercisable at December 31, 2021:

	Options Outstanding			Options Exercisable		
Exercise Price	Total Shares	Weighted Average Remaining Contractual Term *(in years)*	Weighted Average Exercise Price	Total Shares	Weighted Average Remaining Contractual Term *(in years)*	Weighted Average Exercise Price
$1.73 to $2.87	215,000	9.89	$ 1.81	—	0.00	$ —
$2.88 to $2.93	665,000	9.62	$ 2.88	—	0.00	$ —
$2.94 to $3.01	506,000	8.95	$ 2.97	253,000	8.95	$ 2.97
$3.02 to $16.15	475,076	7.32	$ 9.97	207,374	6.15	$ 11.97
$16.16 to $234.70	279,542	5.82	$ 84.39	257,749	5.71	$ 88.94
Total	2,140,618	8.48	$ 15.01	718,123	6.98	$ 36.42

The following table summarizes the stock award activity for all restricted stock units during the year ended December 31, 2021:

Awards	Outstanding Restricted Stock Awards and Units	Weighted-Average Grant Date Fair Value Per Share	Outstanding Aggregate Intrinsic Value (in thousands)	Total Fair Value of Restricted Awards Vested (in thousands)
Balance at December 31, 2019	6,359	$ 92.29	$ 82	
Granted	239,023	$ 4.70		
Vested	(2,309)	$ 96.14	$ 30	$ 222
Forfeited	(113,212)	$ 6.73		
Balance at December 31, 2020	129,861	$ 5.59	$ 458	
Granted	136,626	$ 3.54		
Vested	(126,477)	$ 5.05	$ 413	$ 659
Forfeited	(2,506)	$ 4.85		
Balance at December 31, 2021	137,504	$ 4.06	$ 205	

2014 Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan, the “ESPP”, provides for eligible Company employees, as defined by the ESPP, to be given an opportunity to purchase the Company’s common stock at a discount, through payroll deductions, with stock purchases being made upon defined purchase dates. The ESPP authorizes the issuance of up to 55,000 shares of the Company’s common stock to participating employees and allows eligible employees to purchase shares of common stock at a 15% discount from the lesser of the grant date or purchase date fair market value. For the year ended December 31, 2020, there were 14,975 shares purchased by employees under the ESPP. The ESPP has been suspended since December 2020. As of December 31, 2021, there were 18,488 shares available for issuance under the ESPP.

A summary of activity within the ESPP follows:

	Year Ended	
(in thousands except share data)	December 31, 2021	December 31, 2020
Deductions from employees	$ —	$ 56
Share-based compensation expense recognized	$ —	$ 96
Proceeds received by the Company for ESPP	$ —	$ 78
Weighted-average purchase price per common share	$ —	$ 5.21

Share-Based Compensation Expense

Share-based compensation expense by classification for December 31, 2021 and 2020 are as follows:

	Year Ended	
(in thousands)	December 31, 2021	December 31, 2020
General and administrative	$ 2,275	$ 3,170
Research and development	1,164	1,861
Total	$ 3,439	$ 5,031

At December 31, 2021, total compensation cost not yet recognized was $3.2 million and the weighted-average period over which this amount is expected to be recognized is 1.52 years. The aggregate fair value of options and restricted shares vesting in the years ended December 31, 2021 and 2020 was $4.3 million and $4.8 million, respectively.

NOTE 8 - COMMITMENTS AND CONTINGENCIES

Co-Development and Co-Commercialization Agreement - Adaptimmune Therapeutics plc

On December 16, 2016, the Company entered into a Co-Development and Co-Commercialization Agreement with and Adaptimmune Therapeutics plc (Adaptimmune) in order to facilitate a staged collaboration to evaluate, develop and commercialize next generation T cell therapies. Under the Agreement, the parties agreed to evaluate the Company's GoTCR technology (inducible MyD88/CD40 co-stimulation, or iMC) with Adaptimmune's affinity-optimized SPEAR® T cells for the potential to create enhanced TCR product candidates. Depending on results of the preclinical proof-of-concept phase, the parties expect to progress to a two-target co-development and co-commercialization phase. To the extent necessary, and in furtherance of the parties' proof-of-concept and co-development efforts, the parties granted each other a royalty-free, non-transferable, non-exclusive license covering their respective technologies for purposes of facilitating such proof-of-concept and co-development efforts. In addition, as to covered therapies developed under the agreement, the parties granted each other a reciprocal exclusive license for the commercialization of such therapies. With respect to any joint commercialization of a covered therapy, the parties agreed to negotiate in good faith the commercially reasonable terms of a co-commercialization agreement. The parties also agreed that any such agreement shall provide for, among other things, equal sharing of the costs of any such joint commercialization and the calculation of profit shares as set forth in the Agreement. The Agreement will expire on a country-by-country basis once the parties cease commercialization of the T cell therapies covered by the Agreement, unless earlier terminated by either party for material breach, non-performance or cessation of development, bankruptcy/insolvency, or failure to progress to co-development phase.

License Agreement - Baylor

In 2008, 2010, 2014 and 2016, the Company and Baylor College of Medicine ("BCM") entered into license agreements pursuant to which the Company obtained exclusive rights to certain technologies and patent rights owned by BCM.

Under the 2014 license agreement, the Company is required to pay BCM a low annual maintenance fee on each anniversary of the agreement date. The Company is also required to make royalty payments in the low single digits, subject to certain annual minimums, on net sales of products covered by the license and, to the extent the Company enters into a sublicensing agreement relating to a licensed product, the Company is also required to pay BCM a percentage in the low double-digits on all non-royalty income received from sublicensing revenue.

During the second quarter of 2021, the Company determined that $0.6 million of sublicense expense was incurred in 2019 through 2020 related to the Company's obligation to pay BCM a percentage of sublicense revenue earned by the Company under the 2014 license agreement. Management evaluated the impact of the adjustment and determined that the amount was immaterial to the consolidated financial statements for the current year and prior years. As such, the entire amount of $0.6 million was recorded during the second quarter in 2021. During the third quarter of 2021, the Company earned additional sublicense revenue and, therefore, recorded additional sublicense expense of $0.5 million.

License Agreement - Agensys, Inc.

On December 10, 2015, the Company and Agensys, Inc. ("Agensys"), entered into a license agreement (the "Agensys Agreement"), pursuant to which (i) Agensys granted the Company, within the field of cell and gene therapy of diseases in humans, an exclusive, worldwide license and sublicense to its patent rights directed to prostate stem cell antigen 1 ("PSCA") and related antibodies, and

(ii) the Company granted Agensys a non-exclusive, fully paid license to the Company's patents directed to inventions that were made by the Company in the course of developing the Company's licensed products, solely for use with Agensys therapeutic products containing a soluble antibody that binds to PSCA or, to the extent not based upon the Company's other proprietary technology, to non-therapeutic applications of antibodies not used within the field. As consideration for the rights granted to the Company under the Agreement, the Company agreed to pay to Agensys a non-refundable upfront fee of $3.0 million, which was included in license fee expense. The Company is also required to make aggregate milestone payments to Agensys of up to (i) $5 million upon the first achievement of certain specified clinical milestones for its licensed products, (ii) $50 million upon the achievement of certain specified clinical milestones for each licensed product, and (iii) $75 million upon the achievement of certain sales milestones for each licensed product. The Agreement additionally provides that the Company will pay to Agensys a royalty that ranges from the mid to high single digits based on the level of annual net sales of licensed products by the Company, its affiliates or permitted sublicensees. The royalty payments are subject to reduction under specified circumstances. These milestone and royalty payments will be expensed as incurred. Under the Agreement, Agensys also was granted the option to obtain an exclusive license, on a product-by-product basis, from the Company to commercialize in Japan each licensed product developed under the Agensys Agreement that has completed a phase 2 clinical trial. As to each such licensed product, if Agensys or its affiliate, Astellas Pharma, Inc., exercises the option, the Agensys Agreement provides that the Company will be paid an option exercise fee of $5 million. In addition, the Agensys Agreement provides that the Company will be paid a royalty that ranges from the mid to high single digits based on the level of annual net sales in Japan of each such licensed product. If the option is exercised, the aggregate milestone payments payable by the Company to Agensys, described above with respect to each licensed product, would be reduced by up to an aggregate of $65 million upon the achievement of certain specified clinical and sales milestones. The Agensys Agreement will terminate upon the expiration of the last royalty term for the products covered by the Agensys Agreement, which is the earlier of (i) the date of expiration or abandonment of the last valid claim within the licensed patent rights covering any licensed products under the Agreement, (ii) the expiration of regulatory exclusivity as to a licensed product, and (iii) 10 years after the first commercial sale of a licensed product. Either party may terminate the Agensys Agreement upon a material breach by the other party that remains uncured following 60 days after the date of written notice of such breach (or 30 days if such material breach is related to failure to make payment of amounts due under the Agensys Agreement) or upon certain insolvency events. In addition, Agensys may terminate the Agensys Agreement immediately upon written notice to the Company if the Company or any of its affiliates or permitted sublicensees commences an interference proceeding or challenges the validity or enforceability of any of Agensys' patent rights.

License Agreement - BioVec

On June 10, 2015, the Company and BioVec Pharma, Inc. ("BioVec") entered into a license agreement (the "BioVec Agreement") pursuant to which BioVec agreed to supply the Company with certain proprietary cell lines and granted to the Company a non-exclusive, worldwide license to certain of its patent rights and related know-how related to such proprietary cell lines. As consideration for the products supplied and rights granted to the Company under the BioVec Agreement, the Company agreed to pay to BioVec an upfront fee of $100,000 within ten business days of the effective date of the BioVec Agreement and a fee of $300,000 within ten business days of its receipt of the first release of GMP lot of the products licensed under the BioVec Agreement. In addition, the Company agreed to pay to BioVec an annual fee of $150,000, commencing 30 days following the first filing of an Investigational New Drug Application (an IND filing), or its foreign equivalent, for a product covered by the license; with such annual fees being creditable against any royalties payable by the Company to BioVec under the BioVec Agreement. The Company also is required to make a $250,000 milestone payment to BioVec for each of the first three licensed products to enter into a clinical phase trial and one-time milestone payments of $2.0 million upon receipt of a registration granted by the Federal Drug Administration or European Medicines Agency on each of the Company's first three licensed products. The BioVec Agreement additionally provides that the Company will pay to BioVec a royalty in the low single digits on net sales of products covered by the BioVec Agreement. The Company may also grant sublicensees under the licensed patent rights and know-how to third parties for limited purposes related to the use, sale and other exploitation of the products licensed under the BioVec Agreement. The BioVec Agreement will continue until terminated. The BioVec Agreement may be terminated by the Company, in its sole discretion, at any time upon 90 days written notice to BioVec. Either party may terminate the BioVec Agreement in the event of a breach by the other party of any material provision of the BioVec Agreement that remains uncured on the date that is 60 days after written notice of such failure or upon certain insolvency events that remain uncured following the date that is 30 days after the date of written notice to a party regarding such insolvency event.

Litigation

On May 29, 2019, Bellicum was served with a second amended complaint indicating that the Company had been added as an additional defendant in an ongoing civil tort lawsuit, captioned Kelly v. Children's Hospital of Los Angeles et al., filed in the Los Angeles County Superior Court, Case No. BC681477. On July 10, 2019 plaintiffs filed a third amended complaint seeking unspecified monetary damages including punitive damages and alleging claims for wrongful death, negligence, breach of fiduciary duty, fraud, medical battery on decedent, medical battery on individual plaintiffs, products liability - failure to warn, breach of express warranty and products liability design or manufacturing defect. Bellicum filed a demurrer and motion to strike plaintiffs' third amended

complaint, which were granted in part on August 5, 2020 with the Court dismissing (without prejudice) all claims against Bellicum with the exception of the breach of express warranty and products liability design or manufacturing defect causes of action. The Court also granted Bellicum's motion to strike plaintiffs' claim for punitive damages. On September 15, 2020, plaintiffs filed a fourth amended complaint alleging the same causes of action and damages against Bellicum as were pled in the third amended complaint. On November 3, 2020, Bellicum filed a demurrer and motion to strike the fourth amended complaint, which is not currently set for hearing but will be rescheduled pursuant to a further order from the court.

NOTE 9 - INCOME TAXES

The reconciliation between federal income taxes at the statutory U.S. federal income tax rate and the Company's income tax expense for the year is as follows:

(in thousands)	December 31, 2021	December 31, 2020
Tax benefit at statutory rate	$ (2,038)	$ (1,658)
Other	4	200
Stock based compensation	780	642
Offering issuance costs and changes in fair value of warrants and private placement option	(3,176)	(9,687)
Deferred tax valuation allowances	4,718	11,690
Research and development credit	(288)	(1,187)
Income tax expense	$ —	$ —

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes, and the amounts used for income tax purposes. Significant components of the Company's deferred taxes as of December 31, 2021 and 2020 are as follows:

(in thousands)	December 31, 2021	December 31, 2020
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 100,346	$ 94,132
Stock compensation	3,541	3,539
Intangible assets	7,156	7,682
Research and development credit	18,076	17,787
Operating lease assets	—	(213)
Operating lease liabilities	—	354
Other	(144)	976
Total deferred tax assets, net of deferred tax liabilities	128,975	124,257
Valuation allowance	(128,975)	(124,257)
Net deferred tax	$ —	$ —

Net operating loss carryforwards and research tax credits as of December 31, 2021 and 2020 are as follows:

(in thousands)	December 31, 2021	December 31, 2020
U.S. federal income tax net operating loss carryforwards	$ 477,839	$ 448,250
U.K. net operating loss carryforwards	$ —	$ 133
U.S. federal research tax credits	$ 12,985	$ 12,535
Texas research tax credits	$ 5,091	$ 5,252

The Company has $228.4 million of U.S. federal net operating loss carryovers that have no expiration date and the remaining begin to expire in 2025. The U.S. Federal and state research credits will begin to expire in 2028 and 2034 respectively. No study has been performed on the research and development (R&D) credits and gross R&D credits in the amount of $17.8 million could be limited based on review by the Internal Revenue Service.

The Internal Revenue Code Section 382 limits NOL and tax credit carry forwards when an ownership change of more than 50% of the value of the stock in a loss corporation occurs. Accordingly, the ability to utilize remaining NOL and tax credit carryforwards may be significantly restricted.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax asset will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during periods in which those temporary differences become deductible.

Due to the uncertainty surrounding the realization of the benefits of its deferred assets, including NOL carryforwards, the Company has provided a 100% valuation allowance on its net deferred tax assets at December 31, 2021 and 2020. The changes in the valuation allowance was an increase of $4.7 million and an increase of $11.7 million for the years ended December 31, 2021 and 2020, respectively.

NOTE 10 - SUBSEQUENT EVENTS

None.

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

None.

ITEM 9A. Controls and Procedures

Management's Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its Principal Executive and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our Chief Executive Officer and our Principal Accounting Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Controls over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Our internal control over financial reporting is designed under the supervision of our management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles.

The Company's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the Consolidated Financial Statements.

Management, including our Chief Executive Officer, has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) in Internal Control-Integrated Framework. Based on those criteria and our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2021.

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be set forth in the sections headed “Election of Directors,” “Information about our Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for our Annual Meeting of Stockholders, or our Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021, and is incorporated herein by reference.

ITEM 11. Executive Compensation

The information required by this item will be set forth in the section headed “Executive and Director Compensation” in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed “Equity Benefit Plans” and “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed “Executive and Director Compensation” in our Proxy Statement and is incorporated herein by reference.

ITEM 13. Certain Relationships and Related Party Transactions, and Director Independence

The information required by this item will be set forth in the sections headed “Certain Relationships and Related Party Transactions” and “Election of Directors” in our Proxy Statement and is incorporated herein by reference.

ITEM 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the section headed “Principal Accounting Fees and Services” in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. Exhibits, Financial Statements and Schedules

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(a)(2) Financial Statement Schedules.

We have omitted these schedules because they are not required, or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

(a)(3) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as amended by Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant and the Second Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report Form 10-Q with the SEC on August 6, 2020).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 5, Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 5, 2019).).
3.3	Certificate of Designations, Preferences and Rights of Series 1 Redeemable Convertible Non-Voting Preferred Stock, Series 2 Redeemable Convertible Non-Voting Preferred Stock and Series 3 Redeemable Convertible Non-Voting Preferred Stock of Bellicum Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's report on Form 8-K, filed with the SEC on August 19, 2019).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	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, as amended (File No. 333-200328), originally filed with the SEC on November 18, 2014).
4.3	Registration Rights Agreement by and among the Registrant and Baker Brothers Life Sciences, LP, and two of its affiliated funds, dated January 15, 2016 (incorporated by reference to Exhibit 4.4 to Registrant's Registration Statement on Form S-3 (File No. 333-209012), filed with the SEC on January 15, 2016).
4.4	Form of Warrant issued in public offering (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.5	Form of Warrant issued in private offering (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.6	Description of Description of Securities (incorporated by reference to Exhibit 4.7 to the Registrant's Current Report on Form 10K (File No. 001-36783), filed with the SEC on March 12, 2020.
4.7	Securities Purchase Agreement, dated August 16, 2019, by and among the Company and the institutional investors named therein, (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.8	Form of pre-funded warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783). filed with the SEC on November 2, 2020).
4.9	Form of warrant to purchase common stock (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No.001-36783), filed with the SEC on November 2, 2020).
4.10	C Form of Pre-Funded Warrant issued in private placement (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).
4.11	Form of Accompanying Common Warrant issued in private placement (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).
4.12	Securities Purchase Agreement dated August 16, 2019, by and among the Company, Baker Brothers Life Sciences, LP, and Boxer Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).

Exhibit Number	Description
10.1+	Form of Indemnification 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, as amended (File No. 333-200328), originally filed with the SEC on November 18, 2014).
10.3+	Bellicum Pharmaceuticals, Inc. 2011 Stock Option Plan and Forms of Incentive Stock Option Grant Agreement and Nonqualified Stock Option Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-200328), originally filed with the SEC on November 18, 2014).
10.4(A)+	Bellicum Pharmaceuticals, Inc. 2014 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 5, 2019).
10.4(B)+	Form of Stock Option Grant Notice and Option Agreement under the 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.4(B) to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2018).
10.4(C)+	Form of Stock Option Grant Notice and Option Agreement under the 2014 Equity Incentive Plan (with accelerated vesting) (incorporated by reference to Exhibit 10.4(C) to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2018).
10.4(D)+	Form of Restricted Stock Award Notice and Restricted Stock Award Agreement under the 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.4(D) to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2018).
10.4(E)+	Form of Restricted Stock Unit Notice and Restricted Stock Unit Agreement under the 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.4(E) to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2018).
10.4(F)+	Form of Stock Option Grant Notice and Option Agreement under the 2014 Equity Incentive Plan (Inducement Award)(incorporated by reference to Exhibit 10.4(F) to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2018).
10.4(G)+	Form of Stock Option Grant Notice and Option Agreement under the 2014 Equity Incentive Plan (Non-Employee Director Form) (incorporated by reference to Exhibit 10.4(G) to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2018).
10.5(A)+	Bellicum Pharmaceuticals, Inc. Bellicum Pharmaceuticals, Inc. 2019 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 8-K filed with the SEC on June 17, 2021).
10.5(B)+	Forms of stock option grant notice, stock option agreement and notice of exercise, and forms of restricted stock award notice and restricted stock award agreement under the Bellicum Pharmaceuticals, Inc. 2019 Equity Incentive Plan.
10.6+	Bellicum Bellicum Pharmaceuticals, Inc. Non-Employee Director Compensation Policy, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with SEC on August 6, 2020).
10.8+	Incentive Award Program, as amended on February 19, 2018 (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2018).
10.9+	Letter Agreement by and between the Registrant and Richard A. Fair, dated January 25, 2017 (incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2017).
10.15	Notice of Expansion of Licensed Field to Obtain Additional Exclusive Rights (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-200328), originally filed with the SEC on November 18, 2014).
10.16*	Amended and Restated License Agreement by and between the Registrant and ARIAD Pharmaceuticals, Inc., dated March 7, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2020).
10.17*	Omnibus Amendment Agreement by and between Registrant and ARIAD Pharmaceuticals, Inc., dated October 3, 2014 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2020).
10.18*	Exclusive License Agreement by and between the Registrant and Baylor College of Medicine, dated March 20, 2008 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2020).

Exhibit Number	Description
10.19*	Exclusive License Agreement by and between the Registrant and Baylor College of Medicine, dated June 27, 2010 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2020).
10.20*	Cancer Research Grant Contract by and between the Registrant and the Cancer Prevention and Research Institute of Texas, dated July 27, 2011 (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2020).
10.21*	Exclusive License Agreement by and between the Registrant and Baylor College of Medicine, effective November 1, 2014 (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed with SEC on November 5, 2020).
10.22*	License Agreement by and between the Registrant and BioVec Pharma, Inc., dated as of June 4, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 13, 2015).
10.23*	Exclusive License Agreement by and between the Registrant and Agensys, Inc., effective as of December 10, 2015 (incorporated by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 14, 2016).
10.24*	Co-Development and Co-Commercialisation Agreement by and between the Registrant and Adaptimmune Limited, effective as of December 16, 2016 (incorporated by reference to Exhibit 10.41 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2017).
10.25^	Master Services Agreement Between The University of Texas M. D. Anderson Cancer Center and Bellicum Pharmaceuticals, Inc.
10.26	Employment Agreement by and between the Registrant and Charity Scripture, dated December 1, 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 the Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance
101.SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation
101.DEF**	XBRL Taxonomy Extension Definition
101.LAB**	XBRL Taxonomy Extension Labels
101.PRE**	XBRL Taxonomy Extension Presentation

+ Indicates management contract or compensatory plan.

* Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant as determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

^ Certain portions of this exhibit have been omitted (indicated by "[***]") because the Company has determined that the information is not material and is the type that the Company treats as private or confidential.

This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

ITEM 15. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Bellicum Pharmaceuticals, Inc.

Date: March 24, 2022

By: /s/ Richard A. Fair
Richard A. Fair
President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard A. Fair as his true and lawful attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorney-in-fact, or his substitute or substitutes may do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Richard A. Fair Richard A. Fair	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 24, 2022
/s/ Charles S. Grass Charles S. Grass	Chief Accounting Officer	March 24, 2022
/s/ James Brown James Brown	Chairman of the Board of Directors	March 24, 2022
/s/ Jon P. Stonehouse Jon P. Stonehouse	Member of the Board of Directors	March 24, 2022
/s/ James M. Daly James M. Daly	Member of the Board of Directors	March 24, 2022
/s/ Stephen R. Davis Stephen R. Davis	Member of the Board of Directors	March 24, 2022
/s/ Reid M. Huber, Ph.D. Reid M. Huber, Ph.D.	Member of the Board of Directors	March 24, 2022
/s/ Judith Klimovsky Judith Klimovsky	Member of the Board of Directors	March 24, 2022

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

Execution Version

MASTER SERVICES AGREEMENT BETWEEN

THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER AND BELLICUM PHARMACEUTICALS, INC.

This Master Services Agreement ("Agreement"), effective as of April 14, 2020 (the "Effective Date"), is made by and between The University of Texas M. D. Anderson Cancer Center ("MD Anderson"), an institution of higher education and one of the institutions of The University of Texas System ("System"), which has its principal address at 1515 Holcombe Boulevard, Houston, Texas 77030, and Bellicum Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 2130 W. Holcombe Boulevard, Suite 800, Houston, Texas 77030 ("Bellicum"). MD Anderson and Bellicum may each be referred to herein as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, MD Anderson is a comprehensive cancer treatment, education, research, and prevention facility and an agency of the State of Texas located in Houston, Texas;

WHEREAS, Bellicum is a clinical stage biopharmaceutical company striving to deliver cures through controllable cell therapies;

WHEREAS, MD Anderson and Bellicum have entered into that certain Asset Purchase Agreement, dated as of January 17, 2020 (as it may be amended from time to time, the "APA"), pursuant to which, among other things, Bellicum agreed to sell the Purchased Assets (as defined in the APA) and to assign the Assumed Liabilities (as defined in the APA) to MD Anderson;

WHEREAS, the execution and delivery of this Agreement was a material inducement to entry into the APA and is a condition to Closing (as defined in the APA) under the terms of the APA;

WHEREAS, in connection with the APA, and pursuant to the terms and subject to the conditions of this Agreement, Bellicum desires for MD Anderson to perform for Bellicum from time to time during the Term, and MD Anderson is willing to perform for Bellicum from time to time during the Term, pursuant to the terms and conditions set forth herein, certain Services as more particularly described in the Work Orders executed by the Parties in accordance with this Agreement;

WHEREAS, in order for MD Anderson to perform the Services, Bellicum will provide MD Anderson with certain Materials as more particularly described herein and in each Work Order; and

WHEREAS, Bellicum desires to engage MD Anderson to perform the Services, and MD Anderson desires to perform the Services, pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms, conditions, benefits and provisions hereof, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby confirm and agree as follows:

AGREEMENT

Section 1. OVERVIEW

1.1 The Services will be described in one or more work orders mutually agreed upon and executed by the Parties pursuant to this Agreement ("Work Orders") and are the subject of this Agreement. Each Work Order shall be in substantially the same form as the "Work Order Template," Exhibit B with such additions and deletions as the Parties may agree.

1.2 Each Work Order executed by the Parties, the schedules, exhibits and attachments referenced in each Work Order and the exhibits referenced in this Agreement are incorporated into this Agreement.

1.3 Other than as described in Section 8.12.F hereof, with regard to the APA, the Agreement shall control and govern all Services performed by MD Anderson under any Work Order. If there is a conflict or inconsistency between the provisions of this Agreement and any Work Order, the terms of the Work Order, including the schedules, exhibits and attachments referenced therein, shall be governed by the terms of this Agreement, unless an individual Work Order expressly and specifically notes the deviations from the terms of the Agreement and exhibits for the purposes of such Work Order in the "Deviations from Terms of Master Services Agreement" section of such Work Order. In the event of a conflict between the Agreement, a Work Order and any Quality Assurance Agreement, if applicable, the terms of the Quality Assurance Agreement shall control.

1.4 All capitalized terms used herein, including the exhibits, schedules and attachments hereto, shall have the meanings specified in the "Definitions," Exhibit A or elsewhere in the Agreement, as applicable, unless otherwise specified.

Section 2. SERVICES

2.1 **Services Generally**. During the Term and in accordance with this Agreement, MD Anderson agrees to provide certain Services, which shall include cell therapy Manufacturing and related activities, as described in Work Orders. MD Anderson and Bellicum have agreed that the scope of Services, including the Initial Supply Commitment and Expansion Option, will be limited to the Manufacture of all Current Bellicum Products and up to two (2) new pre-clinical or clinical stage products. In addition, if either the BPX-601 (within 9 months of the Effective Date) or BPX-603 (within 12 months of the Effective Date) is discontinued for clinical and/or regulatory reasons , Bellicum shall have the right to replace one (1) such discontinued product with another one (1) GoCAR-T product with similar Manufacturing and analytical processes (the "Product Swap"). If Bellicum exercises its right to the Product Swap, then the Parties will negotiate a technical transfer and process introduction plan to be paid by Bellicum at MD Anderson's fully loaded hourly rates. In addition, all engineering, training or qualification runs performed by MD Anderson in connection with such Product Swap shall count toward the Initial Supply Commitment.

2.2 **Initial Supply Commitment**. During the Term, the Parties agree that MD Anderson will Manufacture for Bellicum up to an aggregate of two hundred (200) doses of proprietary cell therapy products (each dose a "Patient Lot") in accordance with, and subject to, the applicable Work Order, provided that Bellicum has complied with all Bellicum Obligations (collectively, the "Initial Supply Commitment"). During the final six (6) months of the Term, no new Work Orders may be requested by Bellicum. For the avoidance of doubt, upon the earlier conclusion of the Term or fulfillment of the Initial Supply Commitment, MD Anderson shall no longer be obligated to perform Services unless otherwise provided in a Work Order, having no obligation to enter into such a Work Order.

2.3 **Delivery, Title and Risk of Loss**.

2.3.A All Deliverables delivered pursuant to any Work Order, including the Patient Lots, shall be Delivered by MD Anderson EX WORKS (Incoterms 2017). Title to and risk of loss with

respect to any Patient Lot or other Deliverable shall pass from MD Anderson to Bellicum at the time such Patient Lot or other Deliverable is released to Bellicum, or Bellicum's carrier, provided that the foregoing shall not relieve MD Anderson of liability arising from MD Anderson's negligence or any failure to comply with its obligations with respect to the proper storage conditions and handling prior to the tender thereof to the carrier. Bellicum shall be responsible for transporting all Deliverables from the Facility to any Bellicum facility at Bellicum's sole cost and expense. MD Anderson will not be responsible for any transportation costs, materials, insurance, or otherwise related to the Deliverables.

2.1.B MD Anderson's responsibility with respect to the care, custody and control of the Materials shall not begin until the Materials have been physically unloaded from trailers and MD Anderson has begun receiving the Materials at the Facility, as evidenced by a duly authorized warehouse receipt.

2.4 **Bellicum Obligations**. For all Services, unless otherwise expressly agreed by the Parties in writing, Bellicum shall (1) pay for and deliver to MD Anderson at the Facility, or other location designated in a Work Order, all Materials in the amounts necessary to meet Bellicum's supply Forecast, (2) provide MD Anderson with all Specifications, including instructions for the Services for the Manufacture of the Deliverables, and ensure MD Anderson has the necessary information to allow MD Anderson to perform the Services in accordance with applicable Work Order and applicable QAA, (3) use commercially reasonable efforts to support MD Anderson in the performance of the Services including knowledge transfer and consultation as reasonably required by MD Anderson, at no charge to MD Anderson, (4) allow for any Lead-Time requirements provided in any Work Order or as otherwise agreed by the Parties,
(5) be responsible for the expiration of any Materials, (6) provide MD Anderson a Forecast as described in the applicable Work Order and Section 2.9 below, (7) be responsible for all technology transfer, process Development, validation or related implementation activities related to or necessary to perform the Services in accordance with the Work Order and Specifications, and (8) ensure all permits or licenses that are held or used by (or which have been filed or delivered by or on behalf of) Bellicum and required for the operation of the Facility or performance of the Services are transferred to MD Anderson including any such permits or licenses required by and in accordance with, the APA (collectively, the "Bellicum Obligations").

2.5 **Materials**. All Materials provided by Bellicum to MD Anderson for use in the Manufacture of Patient Lots shall (1) remain the sole property of Bellicum, (2) be used by MD Anderson only in carrying out its obligations under the Agreement and for no other purpose, (3) not be transferred by MD Anderson to any Third Party that is not specifically authorized in advance and in writing by Bellicum, and (4) unless exhausted in the course of performing the Services, be returned to Bellicum, upon Bellicum's request and at Bellicum's expense, at the expiration or termination of the Agreement or when no longer required to be used under the Agreement. After delivery, MD Anderson will be responsible for storing such Materials for the performance of the Services. Bellicum shall provide MD Anderson with, or ensure MD Anderson has possession of, current, correct and complete Material Safety Data Sheets ("MSD Sheets"), or, if a MSD Sheet is not applicable, then a safety summary sheet which outlines the storage and handling requirements and other characteristics only with respect to those Materials that can be reasonably hazardous in nature (*i.e.*, corrosive, toxic, ignitable, etc.) in order for MD Anderson to safely and properly store and handle such Materials. MD Anderson reserves the right to exclude Materials from the Facility (or require the immediate removal of such Materials) if MD Anderson reasonably determines that it does not have complete and correct information as required by this Section 2.5. Subject to Section 3.7, if Bellicum fails to remove the Materials, MD Anderson may dispose of such Materials in any lawful manner and shall incur no liability due to such disposition. Bellicum grants to MD Anderson a first priority lien upon, and security interest in and to, all Materials at any time deposited in the Facility or any warehouse owned or operated by MD Anderson and in all proceeds and/or products thereof. Such lien and security interest shall secure all fees and charges incurred with respect to Deliverables, whether or not such Deliverable is in MD Anderson's possession or has been Delivered.

2.6 **Standards**. MD Anderson shall perform the Services in accordance with: (1) the Work Order, (2) the Specifications, (3) the QAA, and (4) applicable Laws. MD Anderson will perform the Services in a

professional and workmanlike manner consistent with industry standards applicable to the performance of such Services.

2.7 **Facility**. The Services will be performed at the facility located at 2130 W. Holcombe Boulevard, Houston, Texas 77030 (the "Facility"), unless otherwise specified in a Work Order.

2.7.A **Capacity**. During the Term and at no additional charge to Bellicum, MD Anderson agrees to dedicate capacity equivalent of up to two (2) biomanufacturing suites at the Facility as required, based upon Bellicum's Forecasts, for MD Anderson to meet the Initial Supply Commitment. In order to assure availability of the dedicated capacity, MD Anderson shall ensure that an appropriate biomanufacturing suite is available to Manufacture a Patient Lot, in accordance with a Work Order, within three (3) days after notification by Bellicum.

2.7.B **Expanded Capacity Option**. Bellicum shall have the option to request MD Anderson expand its total capacity described in Section 2.7A, as necessary to meet the capacity requirements of any existing Work Order, up to the equivalent of four (4) suites or two (2) ballrooms. MD Anderson shall allocate such additional capacity for Bellicum, provided (i) new Work Orders for such additional Services are executed by the Parties, (ii) Bellicum fully funds any required build out for such expanded capacity and a reasonable period of time for such building is agreed upon, (iii) Bellicum agrees to pay for all Services performed in such additional space at market value pursuant to a mutually agreed upon Work Order; and (iv) MD Anderson has all necessary rights and permissions (Regental, landlord and otherwise) necessary or required to perform such build out and provide such space, having no obligation to seek any rights or permissions not then presently available under any MD Anderson then-current real property lease for the Facility, (collectively, the "Expansion Option"). Following receipt of Bellicum's notice to exercise the Expansion Option, MD Anderson shall confirm that it has all appropriate rights and permissions for any necessary build out of the space. Upon receipt of MD Anderson's confirmation, Bellicum shall pay MD Anderson an option fee of [***] dollars ($[***]) by wire transfer of immediately available funds to the account described in Section 7.2 hereof. For the avoidance of doubt, notwithstanding a successful exercise of the Expansion Option, upon conclusion of the Initial Term, or fulfillment of the Initial Supply Commitment, MD Anderson shall no longer be obligated to perform Services unless otherwise provided in a Work Order, having no obligation to enter into such a Work Order.

2.8 **Documentation**. MD Anderson shall maintain, and provide to Bellicum, records with respect to the Services and Deliverables in accordance with the QAA.

2.9 **Forecasts.**

2.9.A **Forecasts**. After the Initial Forecast and within the first three (3) Business Days of each month during the Term, Bellicum will provide MD Anderson with monthly rolling forecasts of Bellicum's anticipated Deliverable needs for the following six (6) calendar months (each, a "Forecast"). The first two (2) months of each Forecast will constitute a binding commitment on Bellicum to order the quantity of Deliverables forecasted for such period. For example, a Forecast provided in March will be binding for the months of March and April; accordingly, the Forecast provided in April, shall have the same April Deliverable commitment as provided in the March Forecast, but now the May Forecast will also be binding. However, for each binding month, Bellicum shall be permitted to vary the Forecasted Deliverable amount by up to the greater of 50% of the Deliverables ordered or one (1) Patient Lot. Projections for the non-binding period of each Forecast will constitute Bellicum's reasonable best estimates of future orders, but shall not be binding on Bellicum. To the extent that Bellicum does not order Deliverables consistent with the binding portion of a Forecast, the greater of the Forecasted amount (including the 50% variability described above) or the actual number of orders, will count towards the Initial Supply Commitment. If Bellicum orders more Deliverables than Forecasted (including the 50% variability described above), MD Anderson will use good faith efforts to meet such orders, but the fees charged by MD Anderson for such Services shall be

increased by 50%. For the avoidance of doubt, the following example is for illustrative purposes: if the Forecast for June is four (4) orders of a specific Deliverable, but Bellicum only places two (2) orders of such Deliverable, these orders will be deemed within the accepted variability for such Forecasted amount. However, if Bellicum only places one (1) order of such Deliverable during this month, then Bellicum's order will not be deemed in compliance with the Forecasted amount and the four (4) Forecasted orders will count towards the Initial Supply Commitment. Similarly, if Bellicum places seven (7) orders within this month, then MD Anderson is only obligated to fulfill the six (6) orders which are within the accepted variability, but MD Anderson will use good faith efforts to fulfill the seventh (7^{th}) order; however, such seventh (7^{th}) order, if fulfilled, will be subject to a 50% increase in fees.

2.9.B **Forecast Timing**. Within thirty (30) days of the execution of the first Work Order, Bellicum shall submit to MD Anderson its initial Forecast for each Deliverable under such Work Order (the "Initial Forecast"). Unless otherwise agreed by the Parties, the first month of the Initial Forecast shall commence on the first day of the next calendar month. For all other Work Orders, Bellicum shall submit Forecasts to MD Anderson upon the Work Order effective date or as otherwise mutually agreed in such Work Order. Services shall not begin until after the date covered in the Forecast; provided MD Anderson has received the applicable Forecast prior to such date.

2.10 **Scheduling and Cancellations**.

2.10.A **Scheduling**. For each Patient Lot, Bellicum will notify MD Anderson when it becomes aware of the date on which a patient leukapheresis (the "Patient Apheresis") will occur as well as the arrival date at the Facility. Such notification will occur at least three (3) Business Days prior to arrival of Patient Apheresis at the Facility.

2.10.B **Cancellations**. If, following such initial notification, Bellicum determines that the Patient Apheresis will not be provided and the Patient Lot must be cancelled, Bellicum shall notify MD Anderson as soon as feasible. Upon such cancellation, Bellicum shall be responsible for reimbursement of any costs incurred by MD Anderson in preparation for such cancelled batch, excluding the costs of any Materials (so long as the Materials were provided by Bellicum). The first five (5) cancelled Patient Lots shall not be counted against the Initial Supply Commitment.

Section 3. PRODUCT ACCEPTANCE; DEFECTS; REMEDIES

3.1 **Acceptance of Patient Lots and Other Deliverables.** Bellicum shall examine, inspect and test each Patient Lot or other Deliverable Delivered under the Agreement as soon as practicable after receipt. Bellicum shall notify MD Anderson in writing of any Patient Lot or Deliverable that is Non-Conforming Product within twenty-one (21) calendar days after the date of Delivery ("Acceptance Period"). If such notice is not provided prior to the expiration of the Acceptance Period, the Patient Lot or other Deliverable shall be deemed accepted and to be in conformance with the Agreement.

3.2 **Acceptance of Materials.** MD Anderson shall have the right to examine, inspect and test each Material provided to MD Anderson under the Agreement. MD Anderson shall notify Bellicum in writing of any Material that does not comply with the Specifications for such Material, or meet the requirements described in Section 2.5, and may reasonably reject, or refuse acceptance of, any such Material.

3.3 **Non-Conforming Products.** MD Anderson will not release for Delivery any Non-Conforming Product. In addition, all Patient Lots that are Non-Conforming Products, for which such non-conformance is (a) due to a Process Inherent Issue, or (b) is not due to the negligence or fault of MD Anderson, shall count against the Initial Supply Commitment.

3.4 **Retesting.** In the event Bellicum rejects a Patient Lot or other Deliverable as Non-Conforming Product, MD Anderson shall have the right to sample and retest such Patient Lot or other Deliverable, which shall

be done as soon as practicable and at MD Anderson's expense. In the event of a discrepancy between Bellicum's and MD Anderson's test results such that one Party's results fall within the Specifications and the other Party's test results fall outside the Specifications, or there exists a dispute over whether such failure is due (in whole or in part) to acts or omissions of Bellicum or any Third Party after Delivery, the Parties shall cause a testing laboratory agreeable to both Parties (cost split equally between the Parties, subject to reimbursement as set forth below) to perform comparative tests and/or analyses on samples of the alleged Non-Conforming Product. The testing laboratory's results shall be in writing and shall be final and binding save for manifest error on the face of its report. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the testing laboratory result finally rules and such Party shall reimburse to the other Party the costs advanced to the laboratory pursuant to the foregoing sentence. The testing laboratory shall be required to enter into written undertakings of confidentiality and non-use no less burdensome than set forth or referred to by this Agreement.

3.5 **Remediation.** If any Deliverable is considered Non-Conforming Product, MD Anderson shall, as promptly as reasonably possible, either: (a) remake or produce a new Deliverable, or (b) to the extent it is legally permitted and also reasonably practicable, rework or Reprocess the Patient Lot, so that the Patient Lot or Deliverable (x) can be deemed to have been Manufactured in compliance with cGMP and the agreed Batch Production Record, as applicable, and (y) conforms to the Specifications. The Parties shall agree, in good faith, on the timelines for such resupply or rework.

3.6 **Remediation Costs.**

3.6.A To the extent the non-conformance of any Non-Conforming Product is directly attributable to the negligence or fault of MD Anderson and is not attributable to a Process Inherent Issue, then such resupply or rework Services, as described in Section 3.5 (a) or (b), shall be performed at MD Anderson's cost and expense, including the cost of replacing the Materials. Alternatively, under such circumstances, rather than to have such resupply or rework Services, Bellicum may elect for MD Anderson to refund to Bellicum the amount paid by Bellicum for such Non- Conforming Product, or if payment has not already made, cancel the invoice for such order in which case MD Anderson shall only be responsible for compensating Bellicum for the cost of the Materials.

3.6.B For all Non-Conforming Products, to the extent such non-conformance is not directly attributable to the negligence or fault of MD Anderson, then all such resupply or rework Services as described in Section 3.5 (a) or (b) shall be pursuant to a new Work Order and such Services shall be performed at Bellicum's cost and expense, including the costs of the Materials.

3.7 **Destruction of Non-Conforming Products and Materials**. MD Anderson shall provide reasonable notice to Bellicum of MD Anderson's intent to destroy Non-Conforming Products or Materials (in accordance with Section 2.5) and shall destroy such products unless otherwise instructed by Bellicum in writing within ten (10) days of such notice. If requested by Bellicum within such timeframe, MD Anderson shall make such Non-Conforming Products or Materials available to Bellicum. Bellicum shall have the right to make further use of Non-Conforming Products or Materials for research and Development purposes only, provided that such use does not violate any applicable Laws and in no event is used in connection with human use. In the event that Bellicum desires the use of such Non-Conforming Products or Materials, Bellicum shall pay for any materials, supplies, labor and pass-through testing costs incurred by MD Anderson in connection with the Services related to such products. MD ANDERSON SHALL HAVE NO LIABILITY WHATSOEVER WITH RESPECT TO ANY NON- CONFORMING PRODUCTS OR MATERIALS USED BY, OR AT THE DIRECTION OF BELLICUM SUBSEQUENT TO SUCH REJECTION.

Section 4. FAILURE TO SUPPLY

4.1 In the event MD Anderson is not able to supply, or reasonably anticipates that it will not be able to supply, any Services under any Work Order for any reason, including without limitation force majeure

according to Section 11.8, MD Anderson shall (i) without undue delay provide a written notice (e-mail is sufficient) to Bellicum stating in reasonable detail the cause of such supply inability and the proposed remedial measures and the date such inability is expected to end, and (ii) use commercially reasonable efforts to supply such Services as soon as practicable. The Parties will discuss in good faith all appropriate means of resolving such supply problems.

4.2 In the event that MD Anderson is unable to Manufacture and release three (3) consecutive Patient Lots of the same Deliverable or a total of six (6) Patient Lots of the same Deliverable in any rolling twelve (12) month period as required under a Work Order (excluding, in both circumstances, any Deliverables impacted by Process Inherent Issues), provided all Bellicum Obligations have been successfully met including timely delivery of the Materials to MD Anderson, then a supply interruption shall be deemed to have occurred ("Supply Interruption"). Provided that such Supply Interruption is not (a) caused by force majeure according to Section 11.8, (b) due to the fault of Bellicum or any Third Party, or (c) due to any Process Inherent Issue, a supply failure shall be deemed to have occurred ("Supply Failure"). In the event of a Supply Failure, MD Anderson shall, within sixty (60) calendar days from the beginning of the Supply Failure, prepare an action plan setting forth a proposal to determine the root cause of the Supply Failure and the corrective actions to be taken (the "Action Plan"). The Action Plan shall then be presented to the JSC within such sixty (60) day period. The JSC may accept, modify or reject such Action Plan. In the event the JSC cannot agree upon the proposed (or modified) Action Plan within fourteen (14) days, the matter shall be escalated to the senior management of the Parties in accordance with Section 10.2. If senior management, acting in good faith, cannot agree on an Action Plan within forty- five (45) days from the date of its referral to senior management, then MD Anderson shall have the right to terminate this Agreement upon fifteen (15) days notice.

4.3 Upon determination that a Supply Failure has occurred and is incapable of being cured within sixty (60) days from the date it is deemed a Supply Failure, the Term of such applicable Work Order, as it related to such specific Deliverable, shall be automatically extended for the length of such Supply Failure (unless otherwise terminated in accordance with Section 4.2). For the avoidance of doubt, the length of the Supply Failure arising from the failure to Manufacture and release three (3) consecutive Patient Lots of the same Deliverable, shall commence on the date of the first failed Patient Lot and conclude on the successful implementation of the Action Plan, and the length of the Supply Failure arising from the failure to Manufacture and release a total of six (6) Patient Lots of the same Deliverable in any rolling twelve (12) month period, shall commence on the date of the last failed Patient Lot and conclude on the successful implementation of the Action Plan.

SECTION 5. QUALITY AND REGULATORY MATTERS

5.1 **Quality Assurance Agreement**. The Parties shall enter into a "Quality Assurance Agreement" ("QAA") no later than seven (7) calendar days before the start of any Work Order for Manufacturing of any Deliverable. The QAA shall set forth the Parties' rights and obligations with regard to quality management, quality assurance, quality control, responsibilities of the Parties, documentation, product release procedure including the language of such documentation, regulatory items such as audits and inspections. Upon execution, the QAA for Patient Lots shall be deemed to be incorporated herein as Exhibit C.

5.2 **Process Changes.** Changes to the Existing Process, Services, or Specifications, including changes to any Materials used to Manufacture the Patient Lots or other Deliverable, may only be made in accordance with the QAA. Actual costs incurred as a result of changes will be allocated as follows:

5.2.A MD Anderson shall solely bear all of its actual and related costs resulting from:

(i) Changes to the Facility (including but not limited to changes related to Facility safety) requested by MD Anderson; and

(ii) Changes requested or required by the Governmental Authorities relating to the Facility, and all investments related to the establishment, maintenance and improvement of cGMP.

5.2.B Bellicum shall solely bear all actual and related costs of Bellicum and MD Anderson resulting from:

(i) Changes to the Existing Processes or Services requested by Bellicum, including any changes to the Manufacturing process, Specifications, Materials used to Manufacture the Patient Lots or other Deliverable;

(ii) Changes requested or required by the Governmental Authorities relating to the Existing Process, Services, or Manufacturing process used to Manufacture the Patient Lots or other Deliverable;

(iii) Any technology transfer from a supplier of Materials to another supplier or to MD Anderson (such as, but not limited to, the purchase of any necessary Manufacturing equipment and Manufacturing licenses) to the extent such transfer is authorized by Bellicum.

5.3 **Technical Site Visits by Bellicum (Audits, Person-in-Plant)**

5.3.A **Audits.** In accordance with the terms of the QAA, Bellicum shall be entitled annually to one (1) visit with up to two (2) persons for up to two (2) days to audit the parts of the Facility ("Audit"). Notwithstanding the foregoing, "for-cause" audits may be conducted as described in the QAA.

5.3.B During each audit, Bellicum may inspect corresponding documents (including records) that specifically relate to Manufacturing, quality control, storage, release, complaint/deviation investigations and cGMP activities performed by MD Anderson as related specifically to this Agreement. The right of audit provided herein does not include a right to access or inspect MD Anderson's financial records.

5.3.C In addition to the authorized Audits, in accordance with the terms of the QAA and with at least thirty (30) days advance written notice to MD Anderson, Bellicum shall have the right, at its sole risk and expense, to have one (1) Bellicum employee or agent of Bellicum, who shall be approved by MD Anderson, at the Facility ("Person-in-Plant" or "PIP") during core business hours to observe the production activities and provide support as the single point of contact for such activities.

(i) MD Anderson shall provide adequate office space for the PIP, including access to outside internet connection, and ensure that the PIP is kept reasonably informed of issues that arise that may affect the production or quality of Bellicum product.

5.3.D If an unplanned deviation or other issue arises that reasonably requires the PIP to have access to the Manufacturing facility or QC laboratory, MD Anderson shall grant the PIP reasonable access to those parts of the Facility as needed to evaluate, assess and confirm the satisfactory resolution of such issue.

5.3.E While on MD Anderson's premises, Bellicum shall cause its auditors and PIPs to (i) abide by all applicable Laws, confidentiality obligations to Third Parties and MD Anderson's rules and policies governing its premises, safety and security practices and operating procedures, and (ii) comply with all reasonable instructions of MD Anderson's employees regarding safety and compliance within the premises and the overall use of MD Anderson's premises and equipment, and (iii) operate in a manner as not to adversely interfere with operations at the Facility.

Bellicum shall be solely responsible for the payment and provision to each such auditor and PIP of all compensation and employee benefits, and the withholding and payment of applicable taxes relating to such employment or engagement.

Section 6. TERM OF AGREEMENT

6.1 The initial term of the Agreement will commence on the Effective Date and continue for a period of three (3) years, unless sooner canceled, terminated or extended in accordance with the provisions of this Agreement, including all exhibits attached to and incorporated into this Agreement by this reference thereto (the "Initial Term").

6.1. A Upon implementation of the Expansion Option, the Initial Term shall be extended through (a) the date that is three (3) years from the start of the Expansion Option, or (b) June 30, 2025, whichever comes first (the "Extended Term") (the Initial Term and the Extended Term may be referred herein as the "Term"). In no event shall the Term extend beyond June 30, 2025.

6.2 MD Anderson may suspend the Services performed under the Agreement with immediate effect if at any time MD Anderson reasonably believes, in its sole and absolute discretion, that (a) Bellicum or the Services has a material adverse effect upon MD Anderson, its patients, or personnel; (b) Bellicum or the Services are compromising MD Anderson's established standards of care or performance; (c) the Services do not comply with any Laws of any Government Authority or Regulatory Authority having jurisdiction over the Services; (d) any of the representations or warranties of Bellicum set forth in the Agreement are incomplete, incorrect or inaccurate in any material respect as of any date; (e) any insurance coverage for Bellicum that is required by the Agreement is not in place; (f) Bellicum materially breaches the Agreement; or (g) Bellicum fails to make any payment when due as described in Section

6.3 7.2. MD Anderson shall provide Bellicum thirty (30) days' written notice of such suspension and its rationale and Bellicum shall have the opportunity to cure, if curable, any such issues within that time period unless otherwise extended by written agreement of the Parties. If not cured to MD Anderson's reasonable satisfaction, MD Anderson may terminate the Agreement and shall send Bellicum a written notice of termination which will specify the basis for termination and the effective date of the termination ("Termination Date") (collectively a "Notice of Termination"). In addition, MD Anderson shall have the right to terminate this Agreement and all Services in accordance with Section 4.2.

6.4 Bellicum may terminate the Agreement with immediate effect (i) if any of MD Anderson's representations or warranties set forth in the Agreement are incomplete, incorrect or inaccurate in any material respect as such applicable date, and MD Anderson fails to cure such inaccuracies within 30 days of written notice of such; (ii) the Services do not comply with any Laws of an applicable Governmental Authority or Regulatory Authority having jurisdiction over the Services and MD Anderson fails to cure such noncompliance within 30 days of written notice of such; (iii) upon the occurrence of a material breach of the Agreement by MD Anderson and MD Anderson fails to cure such breach within 30 days of written notice of such; or (iv) a Supply Failure that is not cured within sixty (60) days of written notice of such, or other timeframe as provided for in a JSC-approved action plan. In order for the termination to be effective, Bellicum shall send MD Anderson a Notice of Termination specifying the basis for termination and the Termination Date.

6.5 Either Party may terminate a Work Order at any time and for any reason whatsoever upon thirty (30) days' written notice to the other Party; provided, however, MD Anderson shall not be permitted to terminate any open Work Order related to the Initial Supply Commitment during the Initial Term except in accordance with Section 6.2 above. The Party terminating the Work Order will send the other Party a Notice of Termination which will specify the basis for termination and the effective date of the termination ("Work Order Termination Date"). Termination of a Work Order will not affect any other Work Order pursuant to this Agreement. Neither Party hereto shall by the termination of a Work Order be relieved of its respective obligation and liabilities in any way arising out of or related to the Services performed under such Work Order prior to the Work Order Termination Date, including the payment of

all reasonable costs, fees and expenses incurred by a Party which are directly attributable to any termination for convenience by the other.

6.6 Neither Party hereto shall by the expiration or termination of the Agreement be relieved of its respective obligations and liabilities in any way arising out of or related to the Services performed prior to the Termination Date, including but not limited to the payment by Bellicum to MD Anderson of all reasonable costs, fees and expenses incurred by MD Anderson related to such Services. In addition, in the event the Services are terminated by MD Anderson, Bellicum agrees to pay MD Anderson for all Services completed up through the Work Order Termination Date, any non-cancellable expenses (such as supplies or materials purchased based upon Bellicum's Forecasts, or costs associated with the Expansion Option) and any costs which are directly attributable to any termination by Bellicum. Upon the receipt of a Notice of Termination from Bellicum, MD Anderson should immediately begin to orderly and efficiently wind down the Services to mitigate the fees and expenses paid by Bellicum for the wind down.

6.7 The terms and provisions contained in the Agreement that by their sense and context are intended to survive the performance thereof by either or both Parties shall so survive the completion of performance and termination or expiration of the Agreement, including without limitation, the payment obligations, indemnity obligations, confidentiality provisions and limitations of liability set forth herein.

Section 7. FEES, COSTS, EXPENSES, TAXES, CONSIDERATION AND INVOICING

7.1 For each Patient Lot ordered within the Initial Supply Commitment, Bellicum shall pay MD Anderson the fees described in the applicable Work Order which shall, at a minimum, cover all actual costs to MD Anderson in performing the Services set forth in such Work Order, including but not limited to costs for supplies and consumables (other than the Materials), pass-through expenses, and labor costs. For the avoidance of doubt and unless otherwise specified herein or agreed upon by the Parties, MD Anderson shall not be required to incur any out-of-pocket expenses in performing the Services. For Patient Lots that exceed the Initial Supply Commitment, the Parties agree to negotiate in good faith pricing that appropriately compensates MD Anderson for its performance of such Services, which shall be stated in the applicable Work Order.

7.2 MD Anderson will be compensated for the Services in accordance with the fee schedule set forth in each Work Order or as described herein. Within thirty (30) days from receipt of an invoice, Bellicum shall pay MD Anderson in immediately available funds by wire or electronic fund transfer for all undisputed amounts in each invoice. If Bellicum disputes, in good faith, all or a portion of the charges in an invoice, it shall notify MD Anderson that it disputes certain or all charges in the invoice within 30 days of receipt. For all disputed invoice amounts, the Parties shall seek to resolve the dispute pursuant to the process set forth in Section 11.10 of this Agreement. For any undisputed amounts not paid within 30 days, MD Anderson may charge interest on the past due and undisputed amount at a rate not in excess of the lesser of (a) the "Prime Rate" published in the Wall Street Journal, from time to time, plus one percent (1%), or (b) the maximum rate permitted by law, and Bellicum shall pay all reasonable attorney fees and costs of MD Anderson in enforcing collection of such undisputed amounts owing under the Agreement. All invoices shall be wired to the following account unless otherwise identified in writing by MD Anderson:

JPMorgan Chase Bank, N.A. 707 Travis Street
Houston, Texas 77002

SWIFT: (used for international wires) ABA ROUTING NO.: (used for domestic wires)
ABA ROUTING NO.: (used for domestic Automatic Clearing House) ACCOUNT NAME: **The University of Texas M. D. Anderson Cancer Center** ACCOUNT NO.:
REFERENCE:

The MD Anderson Treasury Services and Operations Department may be contacted at (713) 745-9580 or treasuryservices@mdanderson.org for assistance.

7.3 Taxes. Bellicum shall be responsible for any taxes, duties and charges currently assessed or which may be assessed in the future, that are applicable to the Materials, whether stored at the Facility or otherwise.

Section 8. REPRESENTATIONS, WARRANTIES, LIABILITY AND INDEMNIFICATION

8.1 Bellicum represents, warrants and covenants to MD Anderson that on and as of the date hereof:

8.1.A It is duly formed, validly existing and in good standing under the laws of its state of jurisdiction or formation, with power and authority to carry on the business in which it is engaged and to perform its respective obligations under the Agreement.

8.1.B The execution and delivery of the Agreement by it have been duly authorized and approved by all requisite corporate, limited liability company, partnership, or similar action.

8.1.C It has all the requisite corporate, limited liability company, partnership, or similar power and authority to enter into the Agreement and perform its obligations hereunder.

8.1.D The execution and delivery of the Agreement does not, and consummation of the transactions contemplated herein will not, violate any of the provisions of organizational documents, any agreements pursuant to which it or its property is bound, or, to its knowledge, any applicable laws.

8.1.E The Agreement is valid, binding, and enforceable against it in accordance with its terms subject to bankruptcy, moratorium, insolvency, and other laws generally affecting creditors' rights and general principles of equity (whether applied in a proceeding in a court of law or equity), and the Constitution and laws of the State of Texas;

8.1.F It is qualified to do business in the State of Texas;

8.1.G The Materials delivered to MD Anderson pursuant to the Agreement will, at the time of such delivery, be free and clear of all liens;

8.1.H The Specifications are accurate and complete and includes all instructions and information necessary for MD Anderson to perform the Services; and

8.1.I Any transportation provider or carrier of the Materials or Deliverable has represented and covenanted that it has Business Auto Liability Insurance covering all owned, non-owned or hired automobiles, with limits of not less than $1,000,000 single limit of liability per accident for Bodily Injury and Property Damage.

8.2 MD Anderson represents, warrants and covenants to Bellicum that on and as of the date hereof:

8.2.A MD Anderson has the full power and authority to execute and deliver this Agreement and to perform its obligations under this Agreement (not including the Expansion Option). The

execution and delivery by MD Anderson of this Agreement to be executed and delivered by it, the performance by MD Anderson of its obligations hereunder and the consummation by MD Anderson of the transactions contemplated hereby have been duly and validly authorized. The Agreement is, when executed and delivered by the Parties thereto, the valid and binding obligation of MD Anderson, enforceable against MD Anderson in accordance with its terms;

8.2.B The execution, delivery and performance by MD Anderson of this Agreement, and the consummation of the transactions contemplated hereby, do not conflict with or result in a violation or breach of any provision of any Law or Governmental Order applicable to MD Anderson.

8.2.C To MD Anderson's knowledge, MD Anderson is not under investigation with respect to any violation of any Laws that prevent its performance of the Services.

8.2.D To MD Anderson's knowledge the performance of the Services by MD Anderson complies with all applicable Laws of a Governmental or Regulatory Authority having proper jurisdiction.

8.3 Bellicum warrants, represents, covenants, and agrees that it has all permits, licenses, and approvals required for it to request and receive the Services and has and will otherwise comply with all Laws of all Governmental Authorities and Regulatory Authorities that are now or may, in the future, become applicable to Bellicum, Bellicum's business, equipment, and personnel engaged in Bellicum's business, Bellicum's receipt of the Services or its performance under the Agreement, or arising out of or incident to such performance. Bellicum will perform its obligations under the Agreement in compliance with applicable Laws. To Bellicum's knowledge, Bellicum is not under investigation with respect to any violation of applicable Laws and there are no facts or circumstances that could form the basis for any such violation. Without limiting the generality of foregoing, no bribes, kickbacks, illegal payments, illegal political contributions, or other inappropriate payments, legal or illegal, have been made, directly or indirectly by or on behalf of Bellicum to obtain or retain business, and Bellicum is and has been in compliance with all legal requirements under local anti-corruption and bribery laws, in each case, in jurisdictions in which Bellicum is operating or conducting business (collectively, the "Anti-Bribery Laws"). Bellicum has not received any communication that alleges that Bellicum or any agent of Bellicum is not or may not be in compliance with, or has or may have any liability under, Anti-Bribery Laws. All reports, returns, statements, documents, registrations, filings, and submissions, which are required to be filed with any Governmental Authority relating to Bellicum and Bellicum's business, have been duly and timely filed.

8.4 Bellicum warrants, represents, covenants, and agrees that all information and Materials provided by Bellicum to MD Anderson in connection with the Services to be performed shall be de-identified and aggregated so as to conceal all Protected Health Information ("PHI") as that term is defined in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

8.5 Bellicum warrants, represents, covenants, and agrees that the Materials, Specifications and any other processes or instructions provided to MD Anderson by or on behalf of Bellicum ("Covered Resources") and MD Anderson's use thereof (or access or exercise of any other rights granted under the Agreement with respect to such Covered Resources), and related to performance of the Services, and the MD Anderson's receipt thereof, do not and shall not infringe or misappropriate the Intellectual Property rights of any Third Party, or otherwise conflict with the rights of any Third Party.

8.6 Bellicum warrants, represents, covenants, and agrees that the licenses granted by Bellicum to MD Anderson in Section 9.6.B are the only licenses necessary for MD Anderson to use the Covered Resources in accordance with this Agreement.

8.7 Bellicum warrants, represents, covenants, and agrees that it has disclosed, and will continue to disclose, to MD Anderson, prior to tendering of any Materials to the Facility, any and all potential health, safety and/or environmental hazards that may be associated with transportation, storage or handling of the materials.

8.8 Each Party warrants, represents, covenants, and agrees that: (i) it is not excluded from participation under any state or federal health care program , as defined in 42 U.S.C. §1320a–7b(f), or listed in the U.S. System for Award Management's ("SAM") List of Parties Excluded From Federal Procurement or Non-Procurement Programs, or the United States Office of Inspector General's List of Excluded Individuals/Entities ("LEIE"); and (ii) no final adverse action, as such term is defined under 42 U.S.C. Section 1320a-7e(g), has occurred or is pending or threatened against it (collectively "Excluded/Adverse Actions"). Each Party shall notify the other Party of any Excluded/Adverse Actions or any basis therefore within two (2) days of the notifying Party learning of any such Excluded/Adverse Action or any basis therefore. If a Party is excluded from a state or federal health care program, the other Party may, in addition to any other remedies it may have, immediately terminate the Agreement.

8.9 Each Party shall promptly notify the other Party, in writing, as soon as it becomes aware of any condition or circumstance which makes any of the representations or warranties set forth in the Agreement incomplete, incorrect or inaccurate in any material respect as of any date.

8.10 **MD ANDERSON HAS NOT MADE AND DOES NOT MAKE ANY WARRANTY OR REPRESENTATION WHATSOEVER, EITHER EXPRESS OR IMPLIED, AS TO THE FITNESS, CONDITION, MERCHANTABILITY, DESIGN, OR OPERATION OF THE SERVICES, THEIR FITNESS FOR ANY PARTICULAR PURPOSE, THE QUALITY OR CAPACITY OF THE SERVICES OR WORKMANSHIP IN THE SERVICES, NOR ANY OTHER REPRESENTATION OR WARRANTY WHATSOEVER; BELLICUM ASSUMES ALL RISK AND LIABILITY RESULTING FROM THE USE OF THE SERVICES, INCLUDING RISKS OF DAMAGES, WHETHER USED SINGLY OR IN COMBINATION WITH OTHER PRODUCTS, MATERIALS, OR PERSONAL PROPERTY.**

8.11 **EXCEPT AS PROVIDED FOR IN THE AGREEMENT, IN NO EVENT SHALL MD ANDERSON BE LIABLE FOR ANY LOSS, CLAIM, DAMAGE, OR LIABILITY, OF WHATSOEVER KIND OR NATURE, REGARDLESS OF THE LEGAL THEORY ASSERTED (INCLUDING, WITHOUT LIMITATION, BREACH OF CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR ANY TORT CLAIM), WHICH MAY ARISE FROM OR IN CONNECTION WITH THE AGREEMENT, THE PRESENCE OF PIPS, OBSERVERS, AUDITORS OR OTHER PERSONS ON MD ANDERSON PREMISES OR THE USE, HANDLING OR STORAGE OF MATERIALS, DROP-SHIPPED MATERIALS OR THE SERVICES. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, BELLICUM HEREBY RELEASES MD ANDERSON, SYSTEM, ITS REGENTS, AND THE OFFICERS, AGENTS, AND EMPLOYEES OF MD ANDERSON AND SYSTEM FROM ANY AND ALL LIABILITIES, LOSSES, CLAIMS, OR DAMAGES INCURRED IN CONNECTION WITH THE SERVICES AND THE AGREEMENT.**

8.12 Indemnification.

8.12.A Indemnification by Bellicum. Subject to the other terms and conditions of this Section 8, Bellicum shall indemnify, defend and hold harmless each of MD Anderson, its Affiliates, and each of their respective Regents directors, managers, officers, employees, partners, contractors or agents (collectively, the "MD Anderson Indemnitees") from and against all Losses incurred or sustained by, or imposed upon, any of the MD Anderson Indemnitees or that any of the MD Anderson Indemnitees may incur, as a result of, based upon, arising out of, with respect to, or by reason of, any one or more of the following: (a) any inaccuracy in, or breach of, any of the representations or warranties of Bellicum contained in the Agreement, or in any certificate or instrument delivered by or on behalf of Bellicum pursuant to the Agreement; (b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Bellicum pursuant to the Agreement, or any certificate or instrument delivered by or on behalf of Bellicum pursuant to the Agreement; (c) any fraud, willful misconduct or criminal acts of Bellicum, its Affiliates, or any of the respective Representatives of either, (d) any allegations that the Covered Resources, MD Anderson's use thereof (or access or exercise of any other rights granted under the Agreement with respect to such Covered Resources), or the Services, infringe or violate the

Intellectual Property rights of any Third Party, (e) MD Anderson's performance of the Services in accordance with the Agreement; or (f) the presence of any Bellicum auditors, PIPs or any other Persons authorized or requested by Bellicum, at the Facility or at any other premises owned, leased or operated by MD Anderson; except to the extent any Losses described in (a) through (f) are directly attributable to the gross negligence or willful malfeasance of MD Anderson.

8.12.B Indemnification by MD Anderson. Subject to the Laws and Constitution of the State of Texas and subject to the statutory duties of the Texas State Attorney General, MD Anderson shall defend, indemnify, and hold harmless Bellicum and its Affiliates, and each of their respective their respective directors, managers, officers, employees, partners, contractors or agents (collectively, the "Bellicum Indemnitees") from and against all Losses, and defend Bellicum Indemnitees from all claims, demands, suits, actions or other proceedings, as a result of, based upon, arising out of, with respect to or by reason of any one or more of the following: (a) any inaccuracy in or breach of any of the representations or warranties of MD Anderson contained in the Agreement, or in any certificate or instrument delivered by or on behalf of MD Anderson pursuant to the Agreement; (b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by MD Anderson pursuant to the Agreement; or (c) any fraud, willful misconduct or criminal acts of MD Anderson; except to the extent any Losses described in (a) through (c) are directly attributable to the gross negligence or willful malfeasance of Bellicum

8.12.C Whenever any Actions shall arise for indemnification under this Section 8 (an "Indemnification Claim"), the MD Anderson Indemnitee or the Bellicum Indemnitee, as applicable (the "Indemnified Party"), shall promptly provide written notice of the Indemnification Claim to the other party (the "Indemnifying Party"), but in any event not later than thirty (30) days after the Indemnified Party becomes aware of the Indemnification Claim; *provided* that failure to timely give such written notice shall not relieve the Indemnifying Party of its indemnification obligations except and only to the extent that the Indemnifying Party is required to forfeit rights or defenses by reason of such failure. Such notice shall describe the Indemnification Claim in reasonable detail, shall include copies of all available material written evidence thereof and shall indicate the estimated amount, if reasonably practicable, of the Loss that has been or may be sustained by the Indemnified Party.

8.12.D If Bellicum is the Indemnifying Party, it shall not be entitled to participate in the defense of any MD Anderson Indemnitee with respect to any Indemnification Claim, and will have no right to defend any MD Anderson Indemnitee against the Indemnification Claim. With respect to a Indemnification Claim arising under Section 8.12.A, the MD Anderson Indemnitees will, together with the Attorney General of the State of Texas, undertake the defense, compromise or settlement of each Indemnification Claim on behalf of and for the account and risk of Bellicum as the Indemnifying Party; *provided*, *however*, that no Indemnification Claim shall be compromised or settled without concurrent notice to the Indemnifying Party. Notwithstanding anything to the contrary in this Section 8.12, if the Indemnifying Party is a party to Indemnification Claim, the Indemnifying Party shall be entitled to conduct its own defense of such Indemnification Claim, but not the defense of any MD Anderson Indemnitee concerning such Indemnification Claim. No action taken by any MD Anderson Indemnitee in accordance with such defense and settlement shall relieve the Indemnifying Party of its indemnification obligations herein provided with respect to any damages resulting therefrom.

8.12.E The Indemnifying Party shall cooperate in all commercially reasonable respects with the Indemnified Party and the Attorney General of the State of Texas (as applicable) in the investigation, trial and defense of any Action that may be subject to this Section 8.12 and any appeal arising therefrom. The Parties shall cooperate with each other in any notifications to insurers. The Indemnifying Party shall assist and cooperate, at the cost of the Indemnifying Party, with the Indemnified Party in the making of settlements and the enforcement of any right

of contribution to which any Indemnified Party may be entitled from any Person in connection with the subject matter of any litigation subject to indemnification hereunder.

8.12.F Bellicum and MD Anderson acknowledge and agree that the APA, including, but not limited to, its Section 2 and Section 7, provides an independent indemnification remedy and procedure that is in addition to, and not superseded by, that provided by this Section 8. Further, nothing in this Section 8 shall limit MD Anderson's right to seek any equitable relief to which MD Anderson seeks hereunder or to seek any remedy on account of Bellicum's criminal, intentional, fraudulent or willful misconduct.

Section 9. COVENANTS

9.1 **Confidentiality:** During the Term of the Agreement and for a period of two (2) years thereafter, neither Party will at any time, except as required to perform the Services or as authorized in writing by the Party disclosing information ("Disclosing Party"), supply, disclose, use, or otherwise permit access to any information, in whole or in part, that the other Party ("Receiving Party") may acquire by reason of its performance under the Agreement and that concerns or in any way relates to the Disclosing Party, its Affiliates, and their respective regents, directors, officers, employees, or agents, including, without limitation, any information, data, or records pertaining to MD Anderson's faculty, staff, patients, business, or financial affairs, the Services, and MD Anderson's manufacturing processes ("Confidential Information"). The obligations in this Section 9.1 shall not apply to any Confidential Information that
(i) is rightfully already in the Receiving Party's possession at the time of disclosure by Disclosing Party,
(ii)is or later becomes part of the public domain through no fault of Receiving Party, (iii) is received from a Third Party having no obligations of confidentiality to Disclosing Party, (iv) is independently developed by Receiving Party without use of the Confidential Information, or (v) is required by law to be disclosed, provided that (a) Receiving Party provides Disclosing Party prompt written notice before any such disclosure so that it may seek a protective order or other appropriate remedy and (b) Receiving Party complies with any such protective order (or equivalent) imposed on such disclosure. In the event that a protective order or other remedy is not obtained, Receiving Party shall furnish only that portion of the Confidential Information that is legally required to be disclosed in the opinion of Receiving Party's legal counsel. Within ten (10) Business Days after the termination of the Agreement or the request of Disclosing Party, Receiving Party will return or destroy all Confidential Information. Upon Request, Receiving Party shall provide written confirmation, signed by an officer or other authorized representative of Receiving Party, that all such Confidential Information has been destroyed or deleted as required herein. Notwithstanding anything to the contrary herein, (a) Receiving Party shall be permitted to retain one copy of any Confidential Information for legal or regulatory compliance purposes, and (b) Receiving Party shall not be required to alter or destroy backup tapes or other media containing Confidential Information made in the ordinary course of business pursuant to automated archival processes; provided, however, that any Confidential Information retained shall be kept confidential subject to the confidentiality obligations set forth herein. Without prejudice to the rights and remedies otherwise available to the Parties under the Agreement, the Parties shall be entitled to seek equitable relief by way of injunction if the other Party breaches or threatens to breach any of the provisions of this Section 9.1, without the necessity of posting bond or other security. The provisions of this Section 9.1 shall expressly survive the termination of the Agreement. The Receiving Party will use the same measures to protect Disclosing Party's Confidential Information as it uses to protect its own information of a similar nature. Receiving Party will use at least a reasonable standard of care.

9.2 **Public Information:** The Agreement and related information may be subject to public disclosure under Chapter 552, *Texas Government Code*. Bellicum shall be deemed to have knowledge of this law and the means of protecting Bellicum's legitimate interests. Bellicum represents, warrants and agrees that the Agreement can be terminated if Bellicum knowingly or intentionally fails to comply with a requirement of Subchapter J, Chapter 552, *Texas Government Code*. MD Anderson strictly adheres to all statutes, court decisions and the opinions of the Texas Attorney General with respect to disclosure of public information under the Texas Public Information Act (TPIA), Chapter 552, Texas Government Code. In accordance with §§552.002 and 2252.907, Texas Government Code, and at no additional charge to MD Anderson, Bellicum will make any information created or exchanged with MD Anderson pursuant to the

Agreement (and not otherwise exempt from disclosure under TPIA) available in a format reasonably requested by MD Anderson that is accessible by the public.

9.3 **Publicity:** Unless otherwise required by applicable Law or the rules and regulations of any national stock exchange on which the securities of Bellicum are listed, no Party shall make any public announcements in respect of the Agreement or the transactions contemplated hereby or otherwise communicate with any news media without the prior written consent of the other Party, provided that Buyer strictly adheres to all statutes, court decisions and the opinions of the Texas Attorney General with respect to disclosure of public information under the Texas Public Information Act, Chapter 552, Texas Government Code, and that the press statement set forth on Exhibit I to the APA is otherwise hereby preapproved for dissemination. Further, Bellicum will not state or imply that MD Anderson endorses any of Bellicum's products or services. All materials utilizing the name, trademarks, service marks, or symbols of MD Anderson or The University of Texas for any purpose, including, but not limited to, the use in advertising, marketing, and sales promotion materials or any other materials or mediums (such as the internet, domain names, or URL addresses), must be submitted to MD Anderson's Chief Legal Officer for prior written approval at the following address:

Mailing Address: (Via U.S. Mail)
The University of Texas M. D. Anderson Cancer Center ATTN: Chief Legal Officer
7007 Bertner Ave.
Houston, Texas 77030

9.4 **Compliance with Laws, Regulations and Policies:** MD Anderson and Bellicum will cooperate fully in meeting any obligations imposed upon MD Anderson or Bellicum by any Governmental Authority with respect to the Services performed under the terms of the Agreement. This obligation will specifically include, but not be limited to, compliance with the Health Insurance Portability and Accountability Act. Bellicum (and its representatives, agents, employees, and permitted subcontractors) will comply with all applicable MD Anderson rules and policies, including, without limitation, those related to environmental quality, safety, fire prevention, noise, information security, and architectural barriers issued by MD Anderson's Department of Environmental Health and Safety, and those that restrict the use of alcohol on MD Anderson's campus. In the event Bellicum is granted physical access to MD Anderson's assets or facilities, Bellicum shall do so at its sole risk and expense.

9.5 **Insurance:**

9.5.A During the Term of the Agreement, Bellicum will carry at least the following insurance, with companies authorized to conduct the business of insurance in the State of Texas having an A.M. Best Rating of A-VII or better, and in amounts not less than the following minimum limits of coverage:

(i) Workers' compensation insurance, with statutory limits as required by the various laws applicable to Bellicum's employees and subcontractors;

(ii) Commercial General Liability Insurance with limits of not less than:

(a) Each Occurrence Limit $1,000,000

(b) Personal & Advertising Injury $1,000,000

(c) General Aggregate $2,000,000

(d) Products – Completed Operations Aggregate $2,000,000

The required Commercial General Liability policy will be issued on a form that insures Bellicum's liability for bodily injury (including death), property damage, personal and advertising injury assumed under the terms of the Agreement. To the extent Bellicum's Commercial General Liability Insurance is written on a claims-made basis, Bellicum shall purchase an extended reporting period endorsement effective for twenty-four (24) months after the expiration or cancellation of the policy;

(iii) MD Anderson is governed by the Texas Tort Claims Act, which sets forth certain limitations and restrictions on the types of liability and the types of insurance coverage that can be required of MD Anderson.

9.5.B Bellicum will deliver to MD Anderson evidence of insurance on a Texas Department of Insurance approved certificate form verifying the existence and actual limits of all required insurance policies after the execution and delivery of this Agreement. Additional evidence of insurance will be provided verifying the continued existence of all required insurance no later than thirty (30) days after each annual insurance policy renewal. All insurance policies will be endorsed and name MD Anderson and The Board of Regents of the University of Texas System (the "Board") as Additional Insureds for liability caused in whole or in part by Bellicum's acts or omissions with respect to its on-going and completed operations up to the actual liability limits of the required insurance policies maintained by Bellicum. Commercial General Liability will provide Additional Insured endorsement including ongoing and completed operations coverage will be submitted with the Certificates of Insurance. Commercial General Liability will be endorsed to provide primary and non-contributory coverage. Bellicum hereby waives all rights of subrogation against MD Anderson. All insurance policies will be endorsed to provide a waiver of subrogation in favor of MD Anderson. No policy will be canceled until after thirty (30) days' unconditional written notice to MD Anderson. All insurance policies will be endorsed to require the insurance carrier providing coverage to send notice to MD Anderson thirty (30) days prior to any cancellation, material change, or non-renewal relating to any insurance policy required in this Section 9.5. Bellicum will pay any deductible for any loss. All deductibles will be shown on the Certificates of Insurance. Bellicum's insurance will be primary and non-contributory to any insurance carried or self-insurance program established by MD Anderson or System. Bellicum's insurance will be kept in force until during the Term and for a period of one year thereafter.

9.6 **INTELLECTUAL PROPERTY**

9.6.A All deliverables, results and data generated by MD Anderson, whether patentable or not, in the course of performing the Services hereunder (including, without limitation, all Intellectual Property therein) shall be owned by Bellicum.

9.6.B Bellicum retains all right, title, and interest in and to any Bellicum Intellectual Property. Nothing in the Agreement shall be construed to grant MD Anderson any right or license to any Bellicum Intellectual Property except as expressly set forth herein. During the Term, Bellicum hereby grants to MD Anderson a fully paid, non-exclusive license under any and all Bellicum Intellectual Property and Bellicum Arising IP that is necessary for the sole and limited purpose of MD Anderson's performance of its obligations under the Agreement, including the Services and the Manufacture of Patient Lots.

9.6.C MD Anderson retains all right, title, and interest in and to any MD Anderson Intellectual Property. Any Intellectual Property created or developed solely or jointly by MD Anderson in the course of performing the Services that relates generally to the Development or Manufacture of substances or drug products, including any process, protocol, technology, Know-How or the like that applies generally to the conduct by MD Anderson of laboratory and manufacturing operations and activities, and does not incorporate or utilize Bellicum Confidential Information or Bellicum Intellectual Property, shall be "MD Anderson Arising IP" and MD Anderson shall own all right, title and interest therein. MD Anderson hereby grants to Bellicum a fully paid,

non-exclusive license, to use MD Anderson Arising IP for the sole and limited purposes of the Development, Manufacturing and Commercialization, by or on behalf of Bellicum or a Bellicum sublicensee, of Bellicum the cell therapy products that are the subject of one or more Work Order hereunder.

9.6.D All Intellectual Property created or developed by Bellicum or solely or jointly by MD Anderson in the course of performing the Services that incorporates or utilizes Bellicum Confidential Information or Bellicum Intellectual Property, shall be "Bellicum Arising IP" and the exclusive property of Bellicum. As such, if any such Bellicum Arising IP is created or developed solely by MD Anderson, MD Anderson shall provide written notice to Bellicum of any such Bellicum Arising IP, as soon as possible. MD Anderson hereby assigns to Bellicum all right, title, and interest in and to all such Bellicum Arising IP, and shall take any actions, including but not limited to the execution of documents, reasonably requested by Bellicum and at Bellicum's expense, to effect the purposes of the foregoing.

9.7 **Referrals:** It is understood and agreed by the Parties that: (i) there is no agreement hereunder that either Party refer business to the other Party or any of its Affiliates; (ii) no part of the Services provided or payments made hereunder are intended or should be construed to be in exchange for referrals or arranging referrals; and (iii) payments hereunder represent fair market value determined by the Parties through good faith, arms-length bargaining.

9.8 **Ethics Matters; No Financial Interest:** Bellicum and its employees, agents, and representatives have read and understood the following prior to the commencement of Services under the Agreement: MD Anderson's Ethics Policy, Conflicts of Interest Policy, and Standards of Conduct Guide available at http://www.mdanderson.org/about-us/doing-business/vendors-and-suppliers/index.html and at https://www.mdanderson.org/about-md-anderson/business-legal/conflict-of-interest.html, and applicable state ethics laws and rules available at www.utsystem.edu/ogc/ethics. Neither Bellicum nor its employees, agents, or representatives will assist or cause MD Anderson employees to violate MD Anderson's Ethics Policy, Conflicts of Interest Policy, Standards of Conduct Guide, or applicable state ethics laws or rules. Bellicum represents and warrants that no member of the Board has a direct or indirect financial interest in the transaction that is the subject of the Agreement.

Section 10. GOVERNANCE

10.1 **Joint Steering Committee:** The Parties have formed a Joint Steering Committee (the "JSC"), in which each Party has appointed the following two (2) executive employees as such Party's members of the JSC (the "Members"), all of whom shall be familiar with and have responsibility for oversight of the activities under the Agreement:

MD Anderson:

Bellicum:

Each Party may with written notice to the other Party, change one or more of its Members appointed to the JSC. The JSC shall have general oversight and review of the activities and results under the Agreement and shall be the initial forum for seeking to resolve any issues referred to the JSC by either Party or both. Specifically, but without limitation, the JSC shall seek in good faith to resolve any disputes or issues regarding the Manufacturing schedule or Manufacturing processes for the product.

10.2 **Steering Committee Meetings:** The JSC shall meet, in person or via teleconference or video- conference, on a reasonably regular basis, as planned and agreed by the JSC Members, and in any event within fourteen (14) calendar days after receipt of a written request for such a meeting by one Party to the other Party. The request shall describe the matters or issues to be discussed, including any matter in dispute, and the solution which the requesting Party proposes to be decided. Each Party may invite other

employees to attend the JSC meeting from particular departments/areas of expertise as may be necessary to discuss the agenda topics or matters or issues in dispute. Any action or decision by the JSC shall be taken by unanimous consent of the JSC, with the Members of each Party collectively having a single vote, or by a written resolution signed by all of the Members. If the JSC is unable to reach unanimous consent on a particular matter or issue being discussed by the JSC, then the matter or issues will be referred by each Party to a responsible member of senior management to be designated by each Party, who will use good faith efforts to resolve such matter or issue.

Section 11. GENERAL PROVISIONS

11.1 **Entire Agreement:** The Agreement, read together with the specific provisions of the APA referred to in the Agreement, constitute the entire and complete agreement between the Parties with respect to the subject matter contemplated herein. The Agreement supersedes any prior agreements or understandings, whether written or oral, between the Parties with respect to the Services. To the extent that any provision of the Agreement conflicts with or is inconsistent with the terms of the APA, the APA shall govern.

11.2 **Amendment:** No modification, alteration, waiver, or supplement of the Agreement will be effective unless it is set forth in a written instrument that is signed by both Parties to the Agreement.

11.3 **Independent Contractor:** MD Anderson is an independent contractor with respect to the performance of all Services, and neither MD Anderson nor anyone employed by MD Anderson will be deemed for any purpose to be the employee, agent, servant, or representative of Bellicum in the performance of any Service or any part thereof in any manner dealt with herein. Bellicum will have no direction or control of MD Anderson or its employees and agents. Bellicum will not represent itself to be an agent or representative of MD Anderson or System or the State of Texas. MD Anderson shall never be liable for Bellicum's federal or state income taxes, franchise taxes, or taxes on Bellicum's personnel, including personal income tax and social security taxes associated therewith. Bellicum will cooperate with, and provide reasonable assistance to, MD Anderson in obtaining any tax exemptions to which MD Anderson is entitled.

11.4 **Non-Exclusive Agreement:** Nothing in the Agreement is intended to prevent, or should be construed as preventing, MD Anderson from contracting with any Third Party for the provision of goods or services the same as or similar to the Services. MD Anderson may, notwithstanding anything contained herein to the contrary, engage in whatever activities MD Anderson chooses, in MD Anderson's sole and absolute discretion, whether the same are competitive with Bellicum or otherwise. Bellicum acknowledges and agrees that this Section 11.4 is a material part of the consideration for MD Anderson to enter into this Agreement and to provide the Services.

11.5 **Assignment:** No rights and privileges granted to any Party under the Agreement may be transferred or assigned without obtaining the prior written consent of the other Party. The foregoing prohibition will also apply to any change in control of Bellicum. Any attempt to transfer or assign any rights or privileges under the Agreement without having first obtained written consent from the other Party will be null and void and will entitle the other Party to immediately terminate the Agreement. Notwithstanding anything to the contrary herein, any assignment of the Agreement shall not relieve the assigning Party of its obligations hereunder.

11.6 **Severability:** If any provision of the Agreement is held by a court of competent jurisdiction to be unenforceable, the Agreement shall be deemed to be amended to the extent necessary to make such provision enforceable, or, if necessary, the Agreement shall be deemed to be amended to delete the unenforceable provision or portion thereof. In the event any provision is deleted or amended, the remaining provisions shall remain in full force and effect.

11.7 **Non-Waiver of Defaults:** Failure of any Party to declare any default by any other Party immediately upon occurrence thereof, or delay by any Party in taking any action in connection therewith, will not waive such default or a potential remedy for such default.

11.8 **Force Majeure:** Except for the duty to make payments when due and any indemnification provisions under the Agreement, neither Party will be liable or responsible to the other for any loss or damage or for any delays or failure to perform due to causes beyond its reasonable control, including, but not limited to, acts of God, employee strikes, epidemics, war, riots, flood, fire, sabotage, or any other circumstances of like character.

11.9 **Notices:** Any notice required or permitted to be sent under the Agreement will be delivered by hand, mailed by a nationally recognized overnight courier service (delivery receipt requested) with charges paid by the dispatching Party, or mailed by registered or certified mail, return receipt requested, to Bellicum or to MD Anderson, as the case may be, at the respective notice addresses identified in this Section 11.9. Notice so mailed will be deemed effective (A) upon hand delivery, (B) on the scheduled date of delivery by a nationally recognized overnight courier service, or (C) on the third (3rd) day following the date of deposit into the United States mail.

BELLICUM:

Bellicum Pharmaceuticals, Inc. 2130 West Holcombe Blvd
Suite 800
Houston, TX 77030 Attention: General Counsel

with a copy to:

Pillsbury Winthrop Shaw Pittman LLP 2 Houston Center
909 Fannin Street, Suite 2000
Houston, TX 77010-1028 Attention: Andrew L. Strong

MD ANDERSON:

Jason Bock, VP & Head, Biologics Prod Dev, Biologics Development MD Anderson Cancer Center
Biologics Development 1515 Holcombe Blvd.
Unit 952
Houston, TX 77030-4009

AND

Legal Services
The University of Texas M. D. Anderson Cancer Center ATTN: Chief Legal Officer
7007 Bertner Avenue
Houston, Texas 77030

Or such other person or address as may be given in writing in accordance with this Section.

11.10 **Dispute Resolution:** To the extent that Chapter 2260, *Texas Government Code*, as it may be amended from time to time ("Chapter 2260"), is applicable to the Agreement and is not preempted by other applicable law, the dispute resolution process provided for in Chapter 2260 will be used by

MD Anderson and Bellicum to attempt to resolve any claim for breach of contract that cannot be resolved in the ordinary course of business. The chief business officer of MD Anderson will examine Bellicum's claim and any counterclaim and negotiate in an effort to resolve the claims. The Parties specifically agree
(i) neither execution of this Agreement by MD Anderson nor any other conduct, action or inaction of any representative of MD Anderson relating to the Agreement constitutes or is intended to constitute a waiver of MD Anderson's or the state's sovereign immunity to suit; and (ii) MD Anderson has not waived its right to seek redress in the courts. Any periods set forth in the Agreement for notice and cure of defaults are not waived.

11.11 **Counterparts; Facsimile Signature:** The Agreement may be executed in any number of counterparts, each of which will for all purposes be deemed an original of the Agreement, but all of which together will constitute one and the same document. The Agreement also may be evidenced by facsimile signature or by e-mail delivery of a ".pdf" format data file, and facsimile or ".pdf" signature page will be deemed to be an original signature and is to be considered to have the same binding effect as the delivery of an original signature on an original contract.

11.12 **Survival:** Expiration or termination of the Agreement will not affect any right or obligation that either Party may have accrued prior to such expiration or termination. In particular, all indemnity provisions of the Agreement will survive the expiration or termination of the Agreement.

11.13 **Governing Law and Venue:** The Agreement will be construed under and in accordance with the laws of the State of Texas without reference to its conflicts of law provisions, and all obligations of the Parties created under the Agreement are performable in Harris County, Texas. Subject to the sovereign immunity of the State of Texas, any lawsuit brought against MD Anderson under the Agreement may only be filed in the State District Court in Harris County, Texas.

11.14 **Loss of Funding:** Performance by MD Anderson under the Agreement may be dependent upon the appropriation and allotment of funds by the Texas State Legislature (the "Legislature") and/or allocation of funds by the Board. If the Legislature fails to appropriate or allot the necessary funds, or the Board fails to allocate the necessary funds, then MD Anderson will issue written notice to Bellicum and MD Anderson may terminate the Agreement without further duty or obligation under the Agreement. Bellicum acknowledges that appropriation, allotment, and allocation of funds are beyond the control of MD Anderson.

11.15 **Certification regarding Boycotting Israel:** Pursuant to Chapter 2270, Texas Government Code, Bellicum certifies that it (1) does not currently boycott Israel, and (b) will not boycott Israel during the Term. Bellicum acknowledges the Agreement may be terminated if this certification is inaccurate or becomes inaccurate at any time during the Term.

11.16 **Certification regarding Business with Certain Countries and Organizations:** Pursuant to Chapter 2252, Texas Government Code, Bellicum certifies that it is not engaged in business with Iran, Sudan, or a foreign terrorist organization. Bellicum acknowledges the Agreement may be terminated if this certification is inaccurate or becomes inaccurate at any time during the Term.

11.17 **Construction**. The Agreement shall not be construed either more favorably for or strongly against either of the Parties based upon which Party drafted it. Every covenant, term, and provision of the Agreement shall be construed simply according to its fair meaning.

11.18 **Headings**. The headings used in the Agreement are used for reference purposes only and do not constitute substantive matters to be considered in construing the terms of the Agreement.

11.19 **State Auditor's Office**. The State Auditor's Office may conduct an audit or investigation in connection with procurements made by MD Anderson as set out in Sections 51.9335(c), 73.115(c) and 74.008(c) of the Texas Education Code. This provision is included in contracts to (1) notify Bellicum that the State

Auditor may require Bellicum to provide records related to the procurement; and (2) to be sure Bellicum notifies any subcontractors about this information.

11.20 **Texas Family Code Child Support Certification**. Pursuant to Section 231.006, Texas Family Code, Bellicum represents and warrants that it is not ineligible to receive the award of or payments under the Agreement and acknowledges and agrees that the Agreement may be terminated and payment withheld if this certification is inaccurate.

11.21 **Texas State Agency:**

11.21.A MD Anderson is an agency of the State of Texas and under the Constitution and laws of the State of Texas possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the Constitution and laws of the State of Texas. Nothing in the Agreement is intended to be, or will be construed as, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision of the Agreement (including, without limitation, any provision pertaining to indemnification, a cap on liability, a limitation of damages, or a waiver or limitation of rights, remedies, representations, or warranties), the provisions of the Agreement as they pertain to MD Anderson are enforceable only to the extent authorized by the Constitution and laws of the State of Texas.

11.21.B Any provision of any applicable law, rule, or regulation that invalidates any provision of the Agreement or would cause one or both of the Parties hereto to be in violation of law will be deemed to have superseded the terms of the Agreement. The Parties, however, will use reasonable efforts to accommodate the terms and intent of the Agreement to the greatest extent possible consistent with the requirements of the law and negotiate in good faith toward amendment of the Agreement in such respect.

11.22 **Rules of Construction**. Interpretation of the Agreement shall be governed by the following rules of construction: (a) words in the singular shall be held to include the plural and vice versa and words of one gender shall be held to include the other gender as the context requires, (b) the word “including” and words of similar import shall mean “including, without limitation,” (c) provisions shall apply, when appropriate, to successive events and transactions, (d) the headings contained herein are for reference purposes only and shall not affect in any way the meaning or interpretation of the Agreement, (e) the words “herein,” “hereto,” “hereinafter” and words of similar import refer to the Agreement as a whole,
(f) ”may” is permissive and “may not” is mandatory, (g) ”will” and “shall” are mandatory, not merely expressions of future intent or expectation, (h) items omitted from non-exclusive lists or examples shall not be deemed to be a purposeful omission of other items in such non-exclusive lists or examples, even if such items were originally included in such lists or examples or discussed between the Parties during the negotiation of the Agreement, and (i) the Agreement was drafted with the joint participation of both Parties and shall be construed neither against nor in favor of either, but rather in accordance with the fair meaning hereof.

[Remainder of page intentionally left blank; Signature page follows]

Having agreed to the foregoing terms, and with the intention of being bound, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER:

By: /s/ Peter W.T. Pisters

Its: President

BELLICUM PHARMACEUTICALS, INC.:

By: */s/ Rick Fair*

Name: Peter W.T. Pisters, M.D.

Name: Rick Fair

Its: President and CEO

Read and Approved:

By: */s/ Jason Bock*

Name: Jason B. Bock, Ph.D.

Its: VP and Head, Biologics Product Development

Reviewed and Approved by UTMDACC Legal Services for UTMDACC Signature:

/s/Kenny Freed 4/14/2020

BELLICUM PHARMACEUTICALS, INC. AMENDED AND

RESTATED EMPLOYMENT AGREEMENT

This AMENDED AND RESTATED EMPLOYMENT AGREEMENT (the "**Agreement**") dated as of November 3, 2021, is entered into by and between Bellicum Pharmaceuticals, Inc. a Delaware corporation, having a location at 3730 Kirby Drive, Suite 1200, Houston, Texas 77098 (the "**Company**") and Charity Scripture, MS, PharmD, BCOP. (the "**Executive**").

WHEREAS, Company and Executive are Parties to that certain Employment Agreement dated June 19, 2020 as amended on September 14, 2020 and January 1, 2021 (the "Original Employment Agreement");

WHEREAS, the Company wishes to continue employing Executive in a new full-time role as Chief Development Officer and to provide Executive with certain compensation and benefits in return for Executive's services, and Executive agrees to be employed by the Company in such capacity and to receive the compensation and benefits on the terms and conditions set forth herein;

WHEREAS, the Company and Executive desire to enter into this Agreement to become effective, subject to Executive's signature below as of December 1, 2021 (the "**Effective Date**") in order to memorialize the revised terms and conditions of Executive's employment by the Company; and

WHEREAS, Executive's agreement to and compliance with the provisions in Sections 9 through 11 of this Agreement are a material factor, material inducement and material condition to the Company's entering into this Agreement.

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein and for other good and valuable consideration, the parties agree that the above-described Original Employment Agreement shall hereby be amended and restated in its entirety as follows:

1. **At-Will Employment**. The Company and Executive acknowledge that either Party has the right to terminate Executive's employment with the Company at any time for any reason whatsoever, with or without cause, subject to the provisions of Section 6 and 7 herein. This at-will employment relationship cannot be changed except in a writing signed by both Executive and the Board of Directors of the Company (or a duly authorized committee thereof, if applicable) (the "**Board**"). Any rights of Executive to additional payments or other benefits from the Company upon any such termination of employment shall be governed by Section 7 of this Agreement.

2. **Position and Location**. Executive's duties under this Agreement shall be to serve on a full-time basis as Chief Development Officer with the responsibilities, rights, authority and duties pertaining to such office as are established from time to time by the Company's Chief Executive Officer ("**CEO**"), and Executive shall report to the CEO. Executive shall also act as an officer and/or director and/or manager of such Affiliates of the Company as may be designated by the CEO from time to time, commensurate with Executive's office, all without further compensation, other than as provided in this Agreement. As used herein, "**Affiliate**" means any entity that directly or indirectly controls, is controlled by, or is under common control with, the

Company. Executive's principal place of business for performance of services to the Company under this Agreement shall be in the San Francisco Bay area. The Company will, from time to time, reasonably require Executive to travel temporarily to other locations, including to the Company's headquarters in Houston, Texas in connection with the Company's business.

3. **Commitment**. Executive will devote substantially all of her business time and best efforts to the performance of her duties hereunder; provided, however, that Executive shall be allowed, to the extent that such activities do not interfere in any material respect with the performance of her duties and responsibilities hereunder and do not conflict with the financial, fiduciary or other interests of the Company (or its Affiliates), as determined in the sole discretion of the CEO, to manage her passive personal investments and to serve on corporate, civic, charitable and industry boards or committees. Notwithstanding the foregoing, Executive agrees that she shall only serve on for-profit boards of directors or for-profit advisory committees if such service is approved in advance in the sole discretion of the CEO.

4. **Compensation**.

(a) Base Salary. During Executive's employment with the Company, the Company shall pay Executive a base salary at the annual rate of $400,000, less payroll deductions and withholdings, which shall be payable in accordance with the standard payroll practices of the Company. Executive's base salary shall be subject to periodic review and adjustment by the Board from time to time in the discretion of the Board.

(b) Performance Bonus. For the applicable period covered by the Company's bonus plan then in effect (currently either on a quarterly or an annual basis) as determined by the Board in its sole discretion (the "**Bonus Period**"), Executive shall be eligible to receive a performance bonus ("**Performance Bonus**") from the Company, based on a target annual bonus equal to forty percent (40%) of Executive's base salary. The Performance Bonus will be based on achievement of individual and/or Company goals established by the Board in its sole discretion in advance of each Bonus Period. Following the close of each Bonus Period, the Board will determine whether Executive has earned a Performance Bonus, and the amount of any such bonus. Payment of the Performance Bonus shall be expressly conditioned upon Executive's employment with the Company on the date that the Performance Bonus is paid, except as provided in Section 7(b)(iv) and Section 7(c) below. The Performance Bonus shall be paid within ninety (90) days after the end of the Bonus Period for which it relates. Executive's target Performance Bonus will be subject to periodic review and adjustment by the Board from time to time.

(c) Reimbursement of Expenses.

(i) The Company shall reimburse Executive for reasonable travel and other business expenses incurred by Executive in the performance of her duties hereunder, in accordance with the Company's policies as in effect from time to time.

(ii) Any reimbursements will be paid to Executive within thirty (30) days after the date Executive submits receipts for the expenses, provided Executive submits those receipts within forty-five (45) days after Executive incurs the expense. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A (as defined in Section 14 below): (i) to be eligible to obtain reimbursement for such expenses

Executive must submit expense reports within forty-five (45) days after the expense is incurred, (ii) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (iii) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (iv) the right to reimbursement under this agreement will not be subject to liquidation or exchange for another benefit.

5. **Benefits.** Subject to applicable eligibility requirements, Executive shall be entitled to participate in all benefit plans and arrangements and fringe benefits and programs that may be provided to senior executives of the Company from time to time, subject to plan terms and generally applicable Company policies. Executive is entitled to participate in personal time off and holiday benefits in accordance with Company policy from time to time for its senior executives.

6. **Termination**.

(a) Termination. The employment of Executive under this Agreement shall terminate upon the earliest to occur of any of the following events:

(i) the death of Executive;

(ii) the termination of Executive's employment by the Company due to Executive's Disability pursuant to Section 6(b) hereof;

(iii) the termination of Executive's employment by Executive for any reason;

(iv) the termination of Executive's employment by the Company without Cause;

(v) the termination of Executive's employment by the Company for Cause pursuant to Section 6(c) after providing the Notice of Termination for Cause pursuant to Section 6(d); or

(vi) the termination of Executive's employment upon mutual agreement in writing between the Company and Executive.

(b) Disability. For purposes of this Agreement, "**Disability**" means that Executive has been unable, for ninety (90) consecutive days, or for periods aggregating one hundred and twenty (120) business days in any period of twelve consecutive months, to perform Executive's duties under this Agreement, as a result of physical or mental impairment, illness or injury, as determined in good faith by the Board. A termination of Executive's employment for Disability shall be communicated to Executive by written notice and shall be effective on the 10th day after sending such notice to Executive (the "**Disability Effective Date**"), unless Executive returns to performance of Executive's duties before the Disability Effective Date.

(c) Cause. For purposes of this Agreement, the term "**Cause**" shall mean (i) Executive's willful misconduct which is demonstrably and materially injurious to the Company's reputation, financial condition, or business relationships; (ii) the failure of Executive to attempt in good faith to follow the legal written direction of the CEO or the Board; (iii) the failure by Executive to attempt in good faith to perform the duties required of her hereunder (other than any

such failure resulting from incapacity due to physical or mental illness) after a written demand for substantial performance is delivered to Executive by the CEO which specifically identifies the manner in which it is believed that Executive has failed to attempt to perform her duties hereunder;
(iv) Executive being convicted of, indicted for, or pleading guilty or nolo contendere to, a felony or any crime involving dishonesty, fraud or moral turpitude; (v) Executive's dishonesty with regard to the Company or in the performance of her duties hereunder, which in either case has a material adverse effect on the Company; (vi) Executive's material breach of this Agreement unless corrected by Executive within ten (10) days of the Company's written notification to Executive of such breach; or, (vii) Executive's failure to comply in any material respect with the Company's policies and/or procedures, unless corrected by Executive within ten (10) days of the Company's written notification to Executive of such breach.

(d) Notice of Termination for Cause. Notice of Termination for Cause shall mean a notice to Executive that shall indicate the specific termination provision in Section 6(c) relied upon and shall set forth in reasonable detail the facts and circumstances which provide a basis for Termination for Cause.

7. **Consequences of Termination of Employment**.

(a) General. If Executive's employment is terminated for any reason or no reason, the Company shall pay to Executive or to Executive's legal representatives, if applicable: (i) any base salary earned, but unpaid; and, (ii) any unreimbursed business expenses payable pursuant to Section 4 hereof and any accrued but unused personal time off benefits and any other payments or benefits required by applicable law (collectively "**Accrued Amounts**"), which amounts shall be promptly paid in a lump sum to Executive, or in the case of Executive's death to Executive's estate. Other than the Accrued Amounts, Executive or Executive's legal representatives shall not be entitled to any additional compensation or benefits if Executive's employment is terminated for any reason other than by reason of Executive's Involuntary Termination (as defined in Section 7(b) below). If Executive's employment terminates due to an Involuntary Termination, Executive will be eligible to receive the additional compensation and benefits described in Section 7(b) and 7(c), as applicable.

(b) Involuntary Termination. If Executive's employment with the Company is terminated by the Company without Cause (and other than as a result of Executive's death or Disability) and provided in any case such termination constitutes a "separation from service", as defined under Treasury Regulation Section 1.409A-1(h)) (a "**Separation from Service**") (such termination an "**Involuntary Termination**"), in addition to the Accrued Amounts, Executive shall be entitled to receive the severance benefits described below in this Section 7(b), subject in all events to Executive's compliance with Section 7(d) below:

(i) Executive shall receive continued payment of Executive's Base Salary (as defined below) for the first twelve (12) months after the date of such termination (the "Severance Period"), paid over the Company's regular payroll schedule;

(ii) Executive shall receive a lump sum amount equal Executive's target Performance Bonus for the applicable Bonus Period in which such termination occurs, pro-rated based on the ratio that the number of days from the beginning of such Bonus Period in which such termination occurs through the date of termination bears to the total number of calendar days

in the Bonus Period (the "Bonus Payment");

(c) Involuntary Termination in Connection with a Change in Control. In the event that Executive's Involuntary Termination occurs immediately prior to, on or within the twelve (12) months following the consummation of a Change in Control (as defined below) and subject in all events to Executive's compliance with Section 7(d) below, then Executive shall be entitled to the benefits provided above in Section 7(b), except that:

(i) the Bonus Payment shall equal the Executive's full target Performance Bonus for one calendar year rather than a pro-rated target bonus; and

(ii) the vesting of all of Executive's outstanding stock options and other equity awards that are subject to time-based vesting requirements shall accelerate in full such that all such equity awards shall be deemed fully vested as of the date of Executive's Involuntary Termination.

For the avoidance of doubt, in no event shall Executive be entitled to benefits under both Section 7(b) and this Section 7(c). If Executive is eligible for benefits under both Section 7(b) and this Section 7(c), Executive shall receive the benefits set forth in this Section 7(c) and such benefits will be reduced by any benefits previously provided to Executive under Section 7(b).

(d) Conditions and Timing for Severance Benefits. The severance benefits set forth in Section 7(b) and Section 7(c) above are expressly conditioned upon: (i) Executive continuing to comply with Executive's obligations under this Agreement, including Sections 8 through 11; and
(ii) Executive signing and not revoking a general release of legal claims in a form provided by the Company (the "**Release**") within the applicable deadline set forth therein and permitting the Release to become effective in accordance with its terms, which must occur no later than the Release Deadline (as defined in Section 14 below). The salary continuation payments described in Sections 7(b) will be paid in substantially equal installments on the Company's regular payroll schedule and subject to standard deductions and withholdings over the Severance Period following termination; *provided, however,* that no payments will be made prior to the effectiveness of the Release. On the effective date of the Release, the Company will pay Executive the salary continuation payments that Executive would have received on or prior to such date in a lump sum under the original schedule but for the delay while waiting for the effectiveness of the Release, with the balance of the payments being paid as originally scheduled. Bonus Payments described in Section 7(b) and 7(c) will be paid in a lump sum cash payment on the first regular payroll date of the Company following the effective date of the Release, but in no event later than March 15 of the year following the year in which Executive's termination of employment occurred. All severance benefits described in this Section 7 will be subject to all applicable standard required deductions and withholdings.

(e) Definitions.

(i) **"Base Salary"** means Executive's annual base salary in effect immediately prior to Executive's termination.

(i) "**Change in Control**" means a "Change in Control" as defined in the Company's 2019 Equity Incentive Plan.

8. **Confidential Information**. "**Confidential Information**" as used in this Agreement, includes but is not limited to, specialized training received by Executive; products already developed or that will be developed by the Company, including but not limited to, products in the field of cancer immunotherapy, including metastatic castrate resistant prostate cancer and graft versus host disease; research and development materials related to the manipulation of dendritic cell signaling pathways to enhance the immune response; research and development materials, electronic databases; computer programs and technologies; marketing and/or scientific studies and analysis; product and pricing knowledge; manufacturing methods; supplier lists and information; any and all information concerning past, present and future customers, referral sources or vendors; contracts and licenses; management structure, company ownership, personnel information (including the performance, skills, abilities and payment of employees); purchasing, accounting and business systems; short and long range business planning; data regarding the Company's past, current and future financial performance, sales performance, and current and/or future plans to increase the Company's market share by targeting specific medical issues, demographic and/or geographic markets; standard operating procedures; financial information; trade secrets, copyrights, derivative works, patents, inventions, know-how, and other intellectual property; business policies; submissions to government or regulatory agencies and related information; methods of operation; implementation strategies; promotional information and techniques; marketing presentations; price lists; files or other information; pricing strategies; computer files; samples; customer originals; or any other confidential information concerning the business and affairs of the Company. The Company's Confidential Information is also comprised of the personal information received from third parties and/or confidential and proprietary information regarding research, products, or clinical trials received from third parties, but only if such confidential information is reduced to writing and marked "Confidential" by the third party. All such confidential information obtained by Executive, whether in writing, any other tangible form of expression or disclosed orally or through visual means or otherwise, and regardless of whether such information bears a confidential or proprietary legend, will be presumed to be Confidential Information. Executive acknowledges that the Confidential Information is vital, valuable, sensitive, confidential and proprietary to Company and provides Company with a competitive advantage. Executive further acknowledges that Company's Confidential Information is dynamic, and constantly changes in nature and/or quantity, given that Company continues to refine its Confidential Information. The obligations specified in this Section 8 shall not apply, and Executive shall have no further obligations under this Agreement with respect to any Confidential Information that: a) is available to the public at the time of disclosure to Executive or becomes publicly known through no breach of the undertakings hereunder by Executive or to the knowledge of Executive, any third party; b) becomes known to Executive through disclosure by sources other than the Company and its Affiliates and in the course of Executive's service to the Company, said sources being under no obligation of confidentiality to the Company with respect to such Confidential Information; c) is approved by the Company for release; or d) has been independently developed by Executive without benefit of the Confidential Information and on Executive's own time and without use of Company resources. Executive understands and agrees that the Company may require her, as a condition to continued employment, to execute and abide by the terms of a standard proprietary information and inventions agreement with the Company which will further set forth the terms of, and prohibit the unauthorized use or disclosure of, the Company's

confidential and proprietary information (the "**PIIA**") and that such PIIA shall become part of this Agreement and Executive's obligations under this Agreement.

9. **Non-Solicitation, Etc**.

(a) Company Promises.

(i) This Agreement is entered into pursuant to Executive's agreement to these non-solicitation provisions. Executive's agreement to the provisions in Sections 9 through 11 is a material condition of the Company's entering into this Agreement and continued employment of Executive.

(b) Executive's Promises. In exchange for the Company's promises listed above and all other consideration provided pursuant to this Agreement, to which these promises are ancillary, Executive promises as follows:

(i) Executive will not, during or after Executive's employment with the Company, use, copy, remove, disclose or disseminate to any person or entity, the Company's Confidential Information, except (i) as required in the course of performing Executive's duties with the Company, for the benefit of the Company, or (ii) when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information, it being understood that Executive will promptly notify the Company of such requirement so that the Company may seek to obtain a protective order.

(ii) Following employment termination, Executive will immediately return to the Company all materials created, received or utilized in any way in conjunction with Executive's work performed with the Company that in any way incorporates, reflects or constitutes Company's Confidential Information.

(iii) Executive acknowledges that the market for the Company's products, services, and activities is global, and that the products, services and/or activities can be provided anywhere in the world. Executive recognizes that the Company draws its customers and/or clients from around the world because it will seek to file patents and run clinical trials in countries around the world and sell its product to consumers around the world and/or pharmaceutical companies located around the world. Moreover, Executive recognizes that the Company's customers may be contacted by telephone, in person, or in writing (including e-mail via the Internet). Executive further acknowledges that due to the international scope of the Company's customer and client base, the following non-solicitation restriction is necessary.

(iv) Executive agrees and acknowledges that Company will not be provided access to Confidential Information, as defined in Section 8, from or belonging to a third party that Executive was exposed to or received from said third party prior to the execution date of this Agreement and that is the subject of any confidentiality requirement of any kind between Executive and said third party. **EXECUTIVE ALSO AGREES TO INDEMNIFY, REIMBURSE, AND HOLD HARMLESS THE COMPANY FOR ALL ATTORNEY FEES, EXPENSES, COSTS, HARM, OR RELATED COSTS TO COMPANY ARISING FROM**

OR AS A RESULT OF ANY ACTUAL CAUSE OF ACTION OR CLAIM BROUGHT AGAINST COMPANY OR EXECUTIVE RELATED TO ANY ACTUAL BREACH OF THIS SECTION BY EXECUTIVE. Company agrees that: (A) Executive shall be allowed to participate fully in the defense of any such action against Company and in any settlement negotiations, and (B) any payment to Company by Executive under this Section shall be only after any settlement has been consummated or judicial action has become final and non-appealable.

(c) Non-Solicitation of Employees. Executive agrees that during her employment and for twelve (12) months following termination of her employment, Executive will not, directly or indirectly, (i) induce or solicit any person who was an employee, consultant or independent contractor of the Company or any of its Affiliates, to terminate such individual's employment or service with the Company or any of its Affiliates or (ii) assist any other person or entity in such activities.

(d) Extension of Non-Solicitation and Non-Recruitment Periods. If Executive is found by a court of competent jurisdiction to have breached any promise made in Section 9 of this Agreement, the period specified in Section 9(c) of this Agreement shall be extended by one month for every month in which Executive was in breach so that the Company has the full benefit of the time period provided in Section 9(c).

10. **Injunction**. Executive recognizes that Executive's services hereunder are of a special, unique, unusual, extraordinary and intellectual character giving them a peculiar value, the loss of which cannot be reasonably or adequately compensated for in damages. Executive acknowledges that if Executive were to leave the employ of the Company for any reason and compete, directly or indirectly, with the Company, or solicit the Company's employees, or use or disclose, directly or indirectly, the Company's Confidential Information (whether in tangible form or memorized), that such competition, solicitation, use and/or disclosure would cause the Company irreparable harm and injury for which no adequate remedy at law exists. Executive agrees this Agreement is the narrowest way to protect the Company's interests. Therefore, in the event of the breach or threatened breach of the provisions of this Agreement by Executive, the Company shall be entitled to obtain injunctive relief to enjoin such breach or threatened breach, in addition to all other remedies and alternatives that may be available at law or in equity. Executive acknowledges that the remedies contained in this Agreement for violation of this Agreement are not the exclusive remedies that the Company may pursue.

11. **Inventions**.

(a) Inventions Retained and Licensed. Executive has attached hereto as Exhibit A, a list describing all inventions, original works of authorship, derivative works, developments, improvements and trade secrets that (i) were made by Executive prior to her employment with the Company, (ii) belong to Executive, (iii) relate to the Company's proposed business, products or research and development and (iv) are not assigned to the Company hereunder (collectively, "**Prior Inventions**"); or, if no such list is attached, Executive represents that there are no such Prior Inventions. Executive agrees that Executive will not incorporate, or permit to be incorporated, any Prior Invention owned by Executive or in which Executive has an interest into a Company product, process or service without the Company's prior written consent. Nevertheless, if, in the course of Executive's employment with the Company, Executive

incorporates into a Company product, process or service a Prior Invention owned by Executive or in which Executive has an interest, Executive hereby grants to the Company a nonexclusive, royalty-free, fully paid-up, irrevocable, perpetual, transferable, sublicensable, worldwide license to reproduce, make derivative works of, distribute, perform, display, import, make, have made, modify, use, sell, offer to sell, and exploit in any other way such Prior Invention as part of or in connection with such product, process or service, and to practice any method related thereto.

(b) Assignment of Inventions. Executive agrees that Executive will promptly make full written disclosure to the Company, will hold in trust for the sole right and benefit of the Company, and hereby assign to the Company, or its designee, all Executive's right, title, and interest in and to any and all inventions, original works of authorship, derivative works, developments, concepts, modifications, improvements (including improvements to Confidential Information), designs, discoveries, ideas, know-how, trademarks, trade dress, trade secrets or other intellectual property, whether or not patentable or registrable under copyright or similar laws, which Executive may solely or jointly conceive or develop or reduce to practice, or cause to be conceived or developed or reduced to practice, whether or not reduced to drawings, written descriptions, documentation or other tangible form, as applicable, during the period of time Executive is employed by the Company (collectively, "**Inventions**"), except as provided in Section 11(f) below. Executive further acknowledges that all original works of authorship which are made by Executive (solely or jointly with others) within the scope of and during the period of Executive's employment with the Company and which are protectable by copyright are "works made for hire" as that term is defined in the United States Copyright Act. Executive understands and agrees that the decision whether or not to commercialize or market any Invention is within the Company's sole discretion and for the Company's sole benefit and that no royalty will be due to Executive as a result of the Company's efforts to commercialize or market any such Invention.

(c) Inventions Assigned to the United States. Executive agrees to assign to the United States government all Executive's right, title, and interest in and to any and all Inventions whenever such full title is required to be in the United States by a contract between the Company and the United States or any of its agencies.

(d) Maintenance of Records. Executive agrees to keep and maintain adequate and current written records of all Inventions during the term of Executive's employment with the Company. The records will be in the form of notes, sketches, drawings and any other format that may be specified by the Board. The records will be available to and remain the Company's sole property at all times.

(e) Patent and Copyright Registrations. Executive agrees to assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in any Inventions and any copyrights, patents, mask work rights or other intellectual property rights relating thereto in any and all countries, including, but not limited to, the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, declarations, assignments and all other instruments that the Company deems necessary in order to apply for and obtain such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Inventions, and any copyrights, patents, mask work rights or other intellectual property rights relating thereto. Executive further agrees that Executive's obligations

to execute or cause to be executed, when it is in Executive's power to do so, any such instrument or papers shall continue after the termination of this Agreement. If the Company is unable because of Executive's mental or physical incapacity or for any other reason to secure Executive's signature to apply for or to pursue any application for any United States or foreign patents or copyright registrations covering any Inventions or original works of authorship assigned to the Company as above, then Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agent and attorney in fact, to act for and in Executive's behalf and stead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent or copyright registrations thereon with the same legal force and effect as if executed by Executive.

(f) Exception to Assignments. Executive understands that the provisions of this Agreement requiring assignment of Inventions to the Company do not apply to any Invention that Executive has developed entirely on Executive's own time without using the Company's equipment, supplies, facilities, trade secret information or Confidential Information (an "**Other Invention**"), except for those Other Inventions that either (i) relate in any way at the time of conception or reduction to practice of such Other Invention to the Company's Business or
(ii) result from any work that Executive performed for the Company. Executive will advise the Company promptly in writing, under a confidentiality agreement, of any Invention that Executive believes constitutes an Other Invention and is not otherwise disclosed on Exhibit A. Executive agrees that Executive will not incorporate, or permit to be incorporated, any Other Invention owned by Executive or in which Executive has an interest into a Company product, process or service without the Company's prior written consent. Notwithstanding the foregoing sentence, if, in the course of Executive's employment with the Company, Executive incorporates into a Company product, process or service and Other Invention owned by Executive or in which Executive has an interest, Executive hereby grants to the Company a nonexclusive, royalty-free, fully paid-up, irrevocable, perpetual, transferable, sublicensable, worldwide license to reproduce, make derivative works of, distribute, perform, display, import, make, have made, modify, use, sell, offer to sell, and exploit in any other way such Other Invention as part of or in connection with such product, process or service, and to practice any method related thereto.

12. **Disputes**. Any dispute or controversy between the Company and Executive, arising out of or relating to this Agreement, the breach of this Agreement, the Company's employment of Executive, or otherwise, shall be settled by binding arbitration conducted by and before a single arbitrator in San Mateo or San Francisco County, California administered by the American Arbitration Association in accordance with its Employment Arbitration Rules (the "AAA Rules") then in effect and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Both Employee and the Company hereby waive the right to a trial by jury or judge, or by administrative proceeding, for any covered claim or dispute. To the extent the AAA Rules conflict with any provision or aspect of this Agreement, this Agreement shall control. The arbitrator shall have the authority to award any remedy or relief that a court of competent jurisdiction could order or grant, including, without limitation, the issuance of an injunction. However, either party may, without inconsistency with this arbitration provision, apply to any court having jurisdiction over such dispute or controversy and seek interim provisional, injunctive or other equitable relief until the arbitration award is rendered or the controversy is otherwise resolved. Except as necessary in court proceedings to enforce this arbitration provision or an award rendered hereunder, or to obtain interim relief, neither a party nor an arbitrator may disclose the

existence, content or results of any arbitration hereunder without the prior written consent of the Company and Executive. All claims, disputes, or causes of action under this Agreement, whether by Employee or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. This Agreement is made under the provisions of the Federal Arbitration Act (9 U.S.C., Sections 1-14) ("FAA") and will be construed and governed accordingly. It is the parties' intention that both the procedural and the substantive provisions of the FAA shall apply. **Questions of arbitrability (that is whether an issue is subject to arbitration under this agreement) shall be decided by the arbitrator.** Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. However, where a party already has initiated a judicial proceeding, a court may decide procedural questions that grow out of the dispute and bear on the final disposition of the matter. Each party shall bear its or her costs and expenses in any arbitration hereunder and one-half of the arbitrator's fees and costs; provided, however, that the arbitrator shall have the discretion to award the prevailing party reimbursement of its or her reasonable attorney's fees and costs, unless such award is prohibited by applicable law. Notwithstanding the foregoing, Executive and the Company shall each have the right to resolve any dispute or cause of action involving trade secrets, proprietary information, or intellectual property (including, without limitation, inventions assignment rights, and rights under patent, trademark, or copyright law) by court action instead of arbitration.

13. **Notices**. All notices given under this Agreement shall be in writing and shall be deemed to have been duly given (a) when delivered personally, (b) three business days after being mailed by first class certified mail, return receipt requested, postage prepaid, (c) one business day after being sent by a reputable overnight delivery service, postage or delivery charges prepaid, or (d) on the date on which a facsimile or e-mail is transmitted to the parties at their respective addresses. Any party may change its address for notice and the address to which copies must be sent by giving notice of the new addresses to the other party in accordance with this Section 13, except that any such change of address notice shall not be effective unless and until received.

If to the Company:

Cooley LLP
4401 Eastgate Mall San Diego, CA 92121
Attention:

If to Executive, to Executive's address on file with the Company

14. **Tax Provisions**.

(a) Section 409A. Notwithstanding anything in this Agreement to the contrary, the following provisions apply to the extent severance benefits provided herein are subject to the provisions of Section 409A of the Code and the regulations and other guidance thereunder and any

state law of similar effect (collectively **"Section 409A"**). Severance benefits shall not commence until Executive's Separation from Service. Each installment of severance benefits is a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), and the severance benefits are intended to satisfy the exemptions from application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if such exemptions are not available and Executive is, upon Separation from Service, a "specified employee" for purposes of Section 409A, then, solely to the extent necessary to avoid adverse personal tax consequences under Section 409A, the timing of the severance benefits payments shall be delayed until the earlier of (i) six (6) months and one day after Executive's Separation from Service, or (ii) Executive' death. Executive shall receive severance benefits only if Executive executes and returns to the Company the Release within the applicable time period set forth therein and permits such Release to become effective in accordance with its terms, which date may not be later than sixty (60) days following the date of Executive's Separation from Service (such latest permitted date, the **"Release Deadline"**). If the severance benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which Executive's Separation from Service occurs, the Release will not be deemed effective any earlier than the Release Deadline. None of the severance benefits will be paid or otherwise delivered prior to the effective date of the Release. Except to the minimum extent that payments must be delayed because Executive is a "specified employee" or until the effectiveness of the Release, all amounts will be paid as soon as practicable in accordance with the schedule provided herein and in accordance with the Company's normal payroll practices. The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

To the extent that any reimbursements payable to Executive under this Agreement are subject to the provisions of Section 409A: (i) to be eligible to obtain reimbursement for such expenses Executive must submit expense reports within forty-five (45) days after the expense is incurred,
(ii) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (iii) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (iv) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(b) Section 280G. If any payment or benefit Executive will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment pursuant to this Agreement or otherwise (a "**Payment**") shall be equal to the Reduced Amount. The "**Reduced Amount**" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the

Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change of control transaction triggering the Payment shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within fifteen
(15) calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause
(x) of the first paragraph of this Section 14(b) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section 14(b) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first paragraph of this Section 14(b), Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

15. **Miscellaneous**.

(a) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California without reference to principles of conflict of laws.

(b) Entire Agreement/Amendments. This Agreement and the instruments contemplated herein contain the entire understanding of the parties with respect to the employment

of Executive by the Company from and after the Effective Date and supersede any prior agreements or promises between the Company and Executive, except for any outstanding stock option or other equity award agreement previously entered into between Executive and the Company. There are no restrictions, agreements, promises, warranties, covenants or undertakings between the parties with respect to the subject matter herein other than those expressly set forth herein and therein. This Agreement may not be altered, modified, or amended except by written instrument signed by the parties hereto.

(c) No Waiver. The failure of a party to insist upon strict adherence to any term of this Agreement on any occasion shall not be considered a waiver of such party's rights or deprive such party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. Any such waiver must be in writing and signed by Executive or an authorized officer of the Company, as the case may be.

(d) Assignment. This Agreement shall be binding upon and inure to the benefit of the Company and Executive and their respective successors, assigns, executors and administrators. This Agreement shall not be assignable by Executive.

(e) Representation. Executive represents that Executive's employment by the Company and the performance by Executive of her obligations under this Agreement do not, and shall not, breach any agreement, including, but not limited to, any agreement that obligates her to keep in confidence any trade secrets or confidential or proprietary information of her or of any other party, to write or consult to any other party or to refrain from competing, directly or indirectly, with the business of any other party. Executive shall not disclose to the Company or use any trade secrets or confidential or proprietary information of any other party.

(f) Successors; Binding Agreement; Third Party Beneficiaries. This Agreement shall inure to the benefit of and be binding upon the personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees legatees and permitted assignees of the parties hereto.

(g) Withholding Taxes. The Company shall withhold from any and all compensation, severance and other amounts payable under this Agreement such Federal, state, local or other taxes as may be required to be withheld pursuant to any applicable law or regulation.

(h) Survivorship. The respective rights and obligations of the parties hereunder, including without limitation Sections 8 through 11 hereof, shall survive any termination of Executive's employment to the extent necessary to the agreed preservation of such rights and obligations.

(i) Counterparts. This Agreement may be signed in counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

(j) Headings. The headings of the sections contained in this Agreement are for convenience only and shall not be deemed to control or affect the meaning or construction of any provision of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the day and year first above written.

By: Bellicum Pharmaceuticals, Inc.

By: */s/ Rick Fair* Name: Rick Fair
Title: President and CEO

/s/ Charity Scripture

Charity Scripture, MS, PharmD, BCOP

EXHIBIT A INVENTIONS

Exhibit 21.1

Subsidiaries of Bellicum Pharmaceuticals, Inc.
as of December 31, 2021

Bellicum Pharma Limited, a private limited company organized under the laws of the United Kingdom

Bellicum Pharma GmbH, a private limited liability company organized under the laws of Germany

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-219020 and 333-232771) of Bellicum Pharmaceuticals, Inc., and

(2) Registration Statements (Form S-8 Nos. 333-201036, 333-216656, 333-218772, 333-220170, 333-223636, 333-225554, 333-231272, 333-232304, 333-232774, 333-236149, 333-241675 and 258778) pertaining to the 2006 Stock Option Plan, 2011 Stock Option Plan, 2014 Equity Incentive Plan, as amended, 2014 Employee Stock Purchase Plan, Bellicum Pharmaceuticals, Inc. 2019 Equity Incentive Plan, and 2019 Equity Incentive Plan of Bellicum Pharmaceuticals, Inc.

of our report dated March 24, 2022, with respect to the consolidated financial statements of Bellicum Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Bellicum Pharmaceuticals, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Houston, Texas
March 24, 2022

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard A. Fair, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bellicum Pharmaceuticals, 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. I am 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. 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 24, 2022

/s/Richard A. Fair

Richard A. Fair
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard A. Fair, principal executive officer and principal officer of Bellicum Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon my knowledge:

(1) this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a)); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 24, 2022

/s/ Richard A. Fair
Richard A. Fair
President and Chief Executive Officer

This certification accompanies the Form 10-K 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 Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.