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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-40045

NEXIMMUNE, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**45-2518457**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9119 Gaither Road Gaithersburg MD	**20877**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (301) 825-9810

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	NEXI	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 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on June 30, 2023, as reported by The Nasdaq Capital Market on such date was approximately $5.8 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of Registrant's Common Stock outstanding as of April 12, 2024 was 1,371,051.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our ability to execute successfully on our strategic realignment announced in November 2022 and our reduction-in-force announced in November 2023, including with respect to our realigned focus on the development of the AIM INJ platform;
- our ability to obtain and maintain regulatory approval of our potential product candidates, including any potential product candidates developed using our AIM INJ platform or any of NEXI-001, NEXI-002 or NEXI-003;
- our ability to successfully commercialize and market our potential product candidates, including any potential product candidates developed using our AIM INJ platform or any of NEXI-001, NEXI-002 or NEXI-003, in each case if approved;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for our potential product candidates, including any potential product candidates developed using our AIM INJ platform or any of NEXI-001, NEXI-002, and NEXI-003, in each case if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize our potential product candidates, including any potential product candidates developed using our AIM INJ platform or any of NEXI-001, NEXI-002 or NEXI-003, in each case if approved;
- our ability to obtain funding for our operations;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- the timing of anticipated regulatory filings;
- the timing of availability of data from our clinical trials;
- the impact of the current market conditions, any pandemics, regional conflicts, sanctions, labor conditions or geopolitical events;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;

- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the future impact of it on our clinical trials, business operations and funding requirements;
- our financial performance; and
- plans and expectations for the proposed dissolution and liquidation.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable as of the date of this Form 10-K, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the Securities and Exchange Commission, or SEC, as exhibits to this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the markets in which we operate and intend to operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

NexImmune, Inc. is referred to in this Annual Report on Form 10-K as the "Company," "NexImmune," "we," "us," and "our."

PART I

Item 1. Business.

Overview

We are a clinical stage biotechnology company developing a novel approach to immunotherapy designed to employ the body's own T cells to generate an antigen-specific cell-mediated immune response with curative potential for the patient.

The backbone of our approach is our proprietary Artificial Immune Modulation, or AIM™, nanoparticle technology platform. The AIM technology enables the rational construction of nanoparticles, or artificial antigen presenting cells, that function as synthetic dendritic cells. Like natural dendritic cells, the AIM nanoparticles employ natural signaling proteins, antigen presentation and co-stimulation, to deliver precise instructions to specific T cells directing a desired immune response.

We believe this is a revolutionary approach to directing antigen-specific T cell function specific to each disease, with several key advantages over other technologies, addressing several limitations and barriers that remain in the field. The AIM platform is designed to:

- Deliver **either "upregulatory" or "downregulatory" messages** to targeted T cells (or T cell populations) to direct an antigen-specific therapeutic response without impairing healthy tissue or immune function. The artificial antigen-presenting cell, or aAPC, nanoparticle employing the activating co-stimulatory signal is used to activate and expand antigen-specific T cells that are intended to fight cancers and infectious diseases. The aAPC nanoparticle constructed with a suppressor or apoptotic co-stimulatory signal is intended to engage or suppress antigen specific autoreactive T cells to treat autoimmune diseases.

- Simultaneously **engage and expand T cells directed at multiple antigens, with the potential to pursue a broad ranges of surface and intercellular targets** in a single product. We believe these attributes are critical to increase durable response in cancer by addressing tumor escape mechanisms and for addressing diverse populations of autoreactive T cells.

- Be an **"off-the-shelf" injectable product** which creates substantial new benefits in terms of ability to scale and commercialize T cell targeting therapies, with advantages in cost, reimbursement, logistics, administration and time to patient delivery. Additionally, this modality unlocks significant potential in autoimmune applications. Taken together, this enables products based on the AIM technology as a way to address scale limitations and reach broader patient populations more effectively.

This technology was originally developed at Johns Hopkins University. It has been further developed and optimized by NexImmune following its formation in 2011. The technology translates into two product modalities that include multi-antigen targeted adoptive cell therapies and multi-antigen targeted injectable off the shelf products. The most advanced programs, NEXI-001 and NEXI-002, are adoptive cell therapies which are currently in Phase 1/II trials. Importantly, these two modalities share the same mechanism of action in engaging and directing the function of antigen specific T cells to achieve the desired goal.

Scientific Context

Directing antigen-specific immune responses is one of the top priorities in the field of immunology. It has been demonstrated by multiple modalities that harnessing the power of the immune system can be a powerful factor in fighting cancers, infectious diseases and autoimmune disorders. While advances have been made, new modalities are needed to accelerate progress.

The search for a way to successfully amplify the potential benefits of antigen-specific therapies without impacting the broader immune system has gone on for many years, if not decades.

In Cancer: Some of the greatest progress has been made in blood cancers such as Acute Lymphoblastic Leukemia (ALL), lymphomas and Multiple Myeloma (MM). Novel, single antigen targeting technologies like CAR-Ts and bi-specific T cell engagers (e.g. BiTEs) have demonstrated the ability to target a limited number of well-characterized surface antigens, like CD-19, CD-20 or BCMA. Despite impressive initial clinical response, the lack of durability remains a challenge and has been correlated with tumor escape mechanisms and lack of T cell persistence resulting in relapse. In solid tumors, immune checkpoint inhibitors (CPIs) such as PD-(L)1 and CTLA-4 antibodies are viewed as the most significant breakthrough in

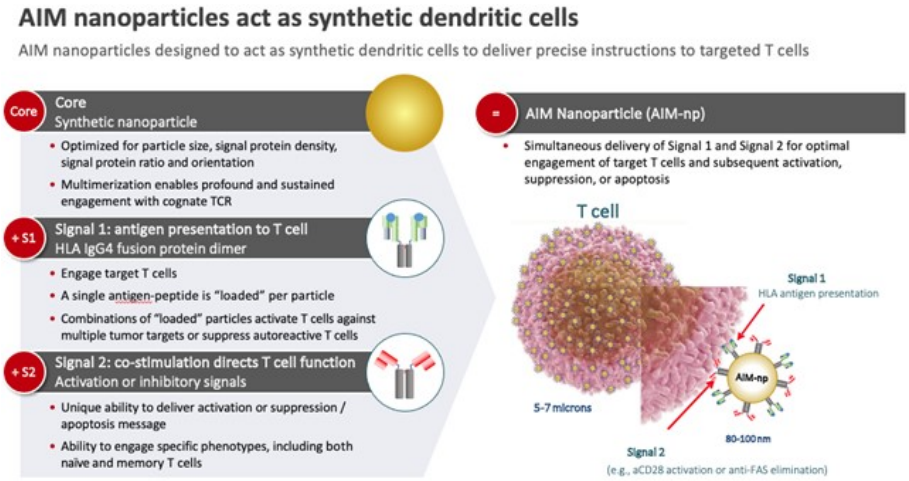
immune-oncology over the last decade. These agents have been approved in many indications as the standard of care. Despite significant progress, it has been reported that the majority of CPI treated patients do not achieve complete response with monotherapy and the addition of chemotherapy has provided only modest improvements. Achieving the next wave of immuno-therapy breakthroughs has been challenging, with a lack of progress in delivering durable anti-cancer response. The need exists for new approaches that can Increase the number of effective tumor-specific T cells, address disease heterogeneity, limit tumor escape and increase T cell persistence for durable response. Ideal approaches would also provide synergistic combinations with existing immunotherapies (IO/IO) to deliver new treatment paradigms.

In autoimmune disorders, the immune cells escape self-regulation (tolerance) and damage healthy tissues and organs. The above learnings from oncology are now being applied to create new possibilities for immune-based treatment. Like in solid tumors, most approved treatments are broad systemic immunosuppressive agents (e.g., TNF, CD-19 or CD20 antibodies). These therapies do not target the disease-causing antigen specific T cells directly. The emerging opportunity is to directly target and inhibit or delete the antigen-specific disease-causing autoreactive T cells and leave healthy tissue alone.

The AIM™ Platform

The AIM technology enables the rational construction of nanoparticles that function as synthetic dendritic cells. These synthetic dendritic cells interact with specific populations of T cells (defined both by antigen specificity and phenotype specificity) to direct a specific T cell function. Typically, this is either a message of activation or suppression.

The following graphic illustrates the critical parts and functions of the nanoparticle (the core and conjugated proteins) as well as the relative size of the nanoparticle to a T cell:

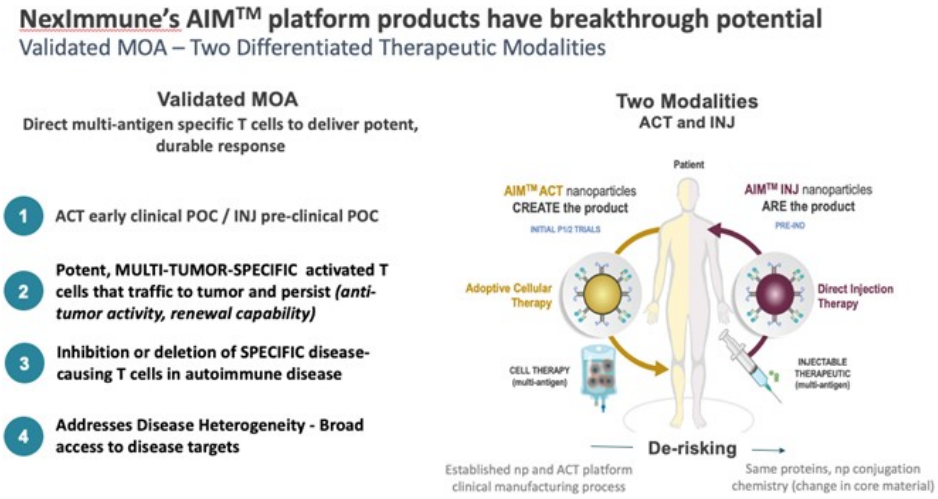


We believe that one of the critical advantages of the AIM technology platform is the modular design enabling the ability to rapidly customize it for new therapeutics. We have developed a rapid antigen peptide loading method that can be used to create new potential products with different antigen targets in months. Some of our collaborations, such as with the target-identifying AI company Zephyr, highlight the potential to validate targets and create therapeutics. We have also developed protein conjugation techniques so that nanoparticles can be customized quickly for different therapeutic goals by changing core materials, Signal 1(HLA alleles) and Signal 2 messages. It is even possible to add additional signals or homing proteins. This gives the platform tremendous flexibility and application.

One of the most significant points of flexibility is that this nanoparticle platform can be used for two therapeutic modalities creating *ex vivo* adoptive cell therapy products or directly injectable, off-the-shelf, *in vivo* T cell therapy products. We call the adoptive cell therapy modality AIM ACT, and the direct-injectable off-the-shelf modality AIM INJ. We have demonstrated both modalities share the same mechanism of action in engaging and directing antigen-specific T cell responses.

Our AIM ACT programs have demonstrated the consistent ability to expand multi-antigen specific T cells across a wide range of intracellular and surface targets. These "fit" specific T cells are polyclonal and include populations with anti-tumor activity, the ability to persist and the capability to self-renewal - attributes known to be associated with durable response. Importantly, AIM ACT T cells have the potential to address both low (cold) and high (hot) immunogenic tumors. We have three clinical stage programs using the AIM ACT modality: NEXI-001 in acute myeloid leukemia, or AML, a low immunogenic tumor, NEXI-002 in relapsed refractory multiple myeloma, or MM, a tumor with a challenging immunosuppressive microenvironment and NEXI-003, in Human papillomavirus, or HPV, related malignancies, a more immunogenic or hot tumor. AIM expanded T cells are derived from the natural T cell repertoire and are capable of discerning between healthy and diseased cells. The importance of "specific" fit anti-tumor T cells is central to IO response. Though enrollment of our clinical programs has been paused due to resource constraints, we observed early dose response and proof of concept which is consistent with pre-clinical data in multiple models.

The AIM INJ modality is a next-generation opportunity to revolutionize multi-antigen-specific T cell therapy. Because we are injecting our antigen-peptide-loaded nanoparticles directly into the body, our products are customizable and off-the-shelf. Importantly, we can deliver up-regulatory or down-regulatory instructions directly to targeted T cells (or T cell populations) regardless of host dendritic cell function without impairing healthy tissue or immune function. With the consistent ability to target multiple antigens in a single product, there is powerful potential to change treatment paradigms in oncology, infectious diseases and autoimmune disorders. We are currently in pre-IND development of INJ technology in multiple diseases (see Pipeline section below) but expect to progress these technologies into clinical trials. We are evaluating the potential to advance our HPV strategy and exploring personalized approaches using the AIM INJ modality.



Our ability to engineer AIM nanoparticles using our platform is expected to also enable rapid new multi-antigen product development. Our nanoparticles are manufactured "unloaded," meaning that while the Signal 1 and Signal 2 proteins are conjugated to the nanoparticle, the specific antigen peptides are not yet loaded into the HLA molecules. The nanoparticles in this form can be stored for significant periods of time. Then, when antigen peptide targets have been identified and validated, the nanoparticles are "loaded", a process that takes hours. The individually loaded nanoparticles can then be mixed to create a disease specific cocktail, which is then vialed and ready for use in manufacturing the T cell product or as an off the shelf injectable product for delivery to the patient. Effectively, this means that the time to product creation depends only on the time to identify and produce the relatively simple antigen-specific peptide (or mix of peptides from multiple antigen targets). This can reduce the time for new multi-antigen-specific product development from years to months. The AIM nanoparticles themselves can be used as a preclinical tool for target validation to expedite the process.

In summary, our AIM nanoparticle technology using our proprietary nano-sized synthetic dendritic cells, has been designed to bypass the host dendritic cells and deliver the right kind of instructions directly to T cells using natural biology.

These nano-sized synthetic dendritic cells are programmed to deliver precise instructions to a specific set of targeted T cells, and these instructions are selected based on the disease and the therapeutic goal.

Our Pipeline

Our pipeline consists of clinical and pre-clinical programs across both the AIM ACT and AIM INJ modality.

We have two ACT multi-antigen product candidates in human clinical trials, NEXI-001 in patients with AML that have relapsed post stem cell transplant and refractory to salvage therapy, and NEXI-002 in patients with MM. Both programs are in Phase I/II trials, have completed the safety evaluation phase and enrollment paused based on resource constraints. We expect to provide an update on these programs in 2024.

The third ACT clinical product candidate, NEXI-003, is our first solid tumor product candidate for HPV related cancers. The investigational new drug application, or IND, has been accepted by the FDA, but this program has also been paused due to resource constraints. Additional pre-IND ACT programs include NEXI-004 for EBV related diseases (cancer, multiple sclerosis) and NEXI-005 designed to select patient specific targets for solid tumors. The ACT oncology portfolio of multi-antigen targeted products is designed to demonstrate durable therapeutic benefit across a range of immunogenic tumor types (cold and hot tumors) and creating IO/IO breakthrough opportunities, including prime treatment strategies when combining these modalities.

We have combined the learning from both modalities including clinical and pre-clinical efforts in oncology which include:

1. Demonstrated proof of concept for the mechanism of action.

2. Ability to expand healthy, fit, antigen-specific T cells from late-stage, heavily pre-treated patients providing insight into the potential to activate healthy, fit, specific T cells *in vivo*.

3. AIM nanoparticles expand “fit” antigen-specific T cells with important subtypes known to be associated with anti-tumor activity and immunologic memory regardless of modality or stage.

4. AIM nanoparticle-expanded T cells proliferate, traffic to tumor site, persist, and maintain both effector and self-renewing populations in both low (cold) and high (hot) immunogenic tumors.

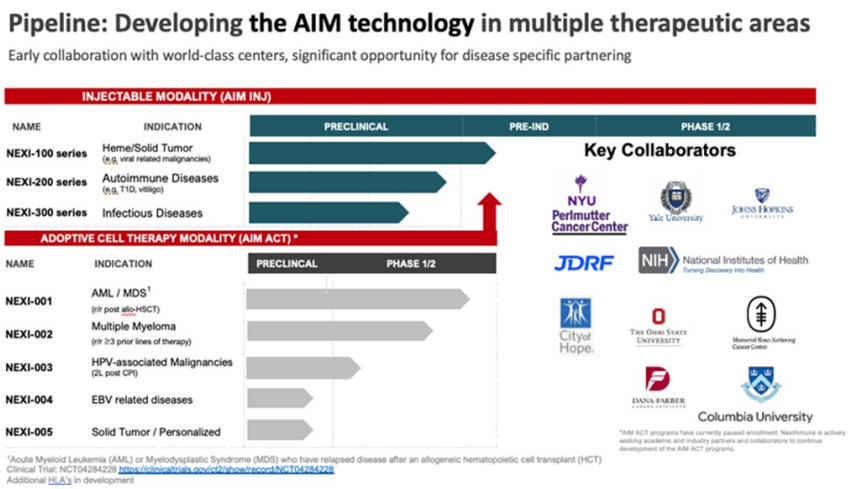
5. No obvious off-tissue toxicity.

6. Potential synergistic effects with superior potency when combining AIM-activated antigen-specific T cells with other IO mechanisms suggesting an increased durable response.

We have prioritized resources to advance the AIM INJ program. We completed substantial non-clinical work to advance the AIM INJ modality towards a potential investigational new drug application, or IND, filing, including preparing appropriate IND-enabling experiments in support of a planned clinical program focusing on solid tumors. Pre-clinical data demonstrate that AIM INJ expands “fit” antigen specific T cells that are cytotoxic, penetrate tumors and persist in animal models. Subject to regulatory feedback and an IND filing, we anticipate a second set of clinical programs that would target autoimmune diseases (e.g. T1D, celiac disease) in which AIM product candidates are designed suppress, rather than activate, T cell function. In support of this potential program, we have generated and published pre-clinical data in which we observed that AIM INJ engaged and suppressed both antigen specific tissue damaging and self-renewing auto-reactive T cells.

Additionally, we are developing the AIM platform for potential clinical application in patients suffering from specific infectious disease. In non-clinical studies, we have been able to expand CD8+ T cells directed against multiple viral antigens simultaneously, including Epstein-Barr virus, Cytomegalovirus, and Human Papillomavirus.

The following table summarizes our pipeline as well as many of our key collaborators:



Our Team and Corporate History

We were founded in 2011, with the exclusive licensing of the core AIM technology from The Johns Hopkins University, or Johns Hopkins. In 2017, attracted by the promise of this technology, Dr. Sol Barer, the co-founder and former Chairperson and Chief Executive Officer of Celgene Corporation, and the current Chairperson of Teva Pharmaceutical Industries Ltd., led the acquisition and recapitalization of our company. Dr. Barer currently serves as Chairperson of our board of directors and has led the recruitment of the management team whose members have decades of experience in the biotechnology industry. Our President and Chief Executive Officer, Kristi Jones, brings over 25 years of biotech leadership in product development, business and strategy roles at Genentech, MedImmune and AstraZeneca PLC. Dr. Jerome (Jerry) Zeldis, M.D., Ph.D., our previous Executive Vice President of Research & Development brings his experience as the former Chief Medical Officer of Celgene and Chief Executive Officer and Chief Medical Officer of Celgene Global Health and continues to support the Company as an advisor. Our previous Chief Medical Officer, Bob Knight, has over 25 years of clinical development experience and joined us from Kite Pharmaceuticals, where he led the clinical development program for Yescarta® and continues to support the existing programs as a consultant. Tim Stover, our Vice President, Corporate Controller and principal financial officer and principal accounting officer, brings over 15 years of accounting, finance, and audit experience serving various life science companies in the U.S. and internationally. Before joining NexImmune, he served as Executive Director, Corporate Controller at Autolus Therapeutics Plc. in London. Mathias Oelke, our Chief Science Officer and scientific co-founder, transitioned from his faculty position with Johns Hopkins to his current position as our Senior Vice President for preclinical immune therapy and platform development.

Our Approach

Our approach to immunotherapy employs the body's own T cells and is designed to generate a disease specific, potent and durable immune response that mimics natural biology. Deploying T cells is natures best mechanism to clear cancer cells. However, when T cells escape immune regulation (tolerance), they become autoreactive (self-damaging) resulting in autoimmune disorders. AIM nanoparticles are designed to direct T cell function using the disease specific antigen presentation to targeted T cells (Signal 1) and a second signal (Signal 2) to provide "instructions" to either clear diseased cells or self-destruct as an innovative approach in cancer, autoimmune disorders and infectious disease. We believe the combination of key attributes creates a unique opportunity to deliver multi-antigen specific immunotherapies with the ability to:

- ***Directly engage and modulate the function of antigen modulate the function of antigen specific T cell populations.*** The AIM nanoparticles are programmed to be antigen specific. That antigen can either be on the T cell itself (in the case of autoreactive T cells) or on a target cell (in the case of oncology or infectious diseases). Importantly, this means that the activation or suppression message is NOT delivered to other cells. The message is for a particular T cell only and does not impact healthy tissue or benign cells.

- ***In cancer, to simultaneously expand multi-tumor antigen specific T cells providing a precise multi-targeted attack on cancer cells*** to increase anti-tumor activity, address tumor heterogeneity and limit tumor escape mechanisms. As we are directing the natural T cell repertoire, our T cells are polyclonal with a broad range of specificities and affinities. Our current clinical programs target five (5) antigens simultaneously, but we have tested higher numbers successfully.

- ***In cancer, consistently expanding "fit" multi-tumor antigen specific T cells*** that include populations of both activated cytotoxic "killer" T cells and T cells with the ability to persist with renewal capacity across a range of "cold" and "hot" tumors. Collectively these T cells populations have been associated with long-term durable response.

- ***In autoimmune disease, to suppress, delete or tolerize multiple disease-causing autoreactive T cells*** that are damaging tissue and organs while reducing disease renewing populations in the lymph nodes. Unlike current therapies, the AIM INJ is not broadly immunosuppressive and does not require other immune cells for activity.

- ***No genetic engineering.*** The AIM technology works by delivering natural signaling to endogenous T cells within the natural repertoire. In ACT, there is no need to genetically alter the T cell offering a more streamline manufacturing process and potential for improved tolerability as a cell therapy. The INJ therapy, "off the shelf", and upon injection directly modulates the natural T cell repertoire in vivo.

- ***"Off-the-shelf" manufacturing and administration.*** The AIM INJ modality is scalable and simple to administer. Nanoparticles can be manufactured ahead of time and stored, enabling a significant cost time and scalability advantage over most other T cell therapies.

- ***Rapid new product development.*** In addition to these core principles of differentiation, we believe the unique modular design of the AIM platform and manufacturing process facilitates the rapid design of new product candidates. This capability is based on synergies derived from interchangeable components (antigen peptides, signaling proteins, core material), shared methods for nanoparticle construction (protein conjugation, peptide loading) and a platform cell therapy manufacturing system. Rather than having to create a fully new biologic molecule, like an antibody, against the target, the peptides can simply be loaded onto the nanoparticles for immediate testing as a new product.

While there are many T cell focused technology platforms and product candidates in development across the biotechnology industry, we believe that the AIM nanoparticle T cell directed approach has a unique combination of attributes with the potential to be transformative in the field of immunotherapy.

Our Strategy

Our mission is to create therapies with curative potential for patients with cancer and other life-threatening immune-mediated diseases. We believe that in the long term, our AIM technology has the potential to be a core component of many immunotherapy combinations used to treat a variety of immune-mediated diseases. Our ultimate goal is to develop and bring to patients, independently or working with partners, a portfolio of off-the-shelf T cell products with specific application to a wide range of cancers, autoimmune disorders and infectious diseases.

Key elements of our strategy include:

- ***Advance the AIM INJ program candidates into clinical trials.*** We believe that one of the most significant advantages presented by our AIM technology is the potential for an "off-the-shelf," injectable form of the AIM nanoparticle. Our first program is likely to be in oncology, and our next program likely in the autoimmune disorder space. The specific timing for the start of the clinical trials will depend on resource availability but the development of the AIM INJ product candidates remain our top priority.

- ***Advance NEXI-001 and NEXI-002 to registrational trials.*** While enrollment in both of these programs is currently paused due to resource constraints, we have been generating meaningful proof-of-concept data supporting tolerability, immune response and clinical activity while validating our mechanism of action (MOA). Life Cycle Development Plans to move into earlier lines of therapy and evaluate novel IO/IO combinations in specific populations based on emerging pre-clinical data have also been paused.

- ***Drive forward our solid tumor strategy.*** Our first solid tumor product candidate, NEXI-003 represents the potential to advance IO/IO breakthroughs in HPV related tumors. Our HPV programs are designed to deliver a

potent anti-tumor response against multiple HPV antigens combined with a cancer survival antigen. Additional product candidates using a mix of selected patient specific antigen strategies, including neoantigen approaches and IO/IO combinations are in pre-clinical development using both ACT and the INJ modalities. Our ongoing collaboration with New York University (Dr. Jeff Weber's lab) is advancing our personalized neoantigen strategies and our collaboration with Hackensack Meridian Health Center for Discovery is advancing what we believe to be a unique IO/IO combination, AIM nanoparticle expanded "fit" T cells combined with TCE agents.

- ***Advance multiplex functional target validation.*** We will continue to advance our multiplex functional validation tools that enable enhanced multi-target combinations and selection for new products. Given the large number of potential antigen combinations in solid tumors, and the broad potential in autoimmune disorders and infectious diseases, we expect licensing and partnerships to be a core element of our strategy as we establish the broader applicability of our AIM technology.

- ***Advance our autoimmune strategy and Leverage partnerships to drive early product development.*** The AIM INJ modality has been constructed to deliver either "suppressive" or "apoptotic" co-stimulation signals directly to auto-reactive T cell populations, which is critical for addressing autoimmune disorders. In addition to Class I development, we have designed a Class II nanoparticle that unlocks broad potential in the autoimmune space. Our collaborations with the National Institute of Health, or NIH, for advancing Multiple Sclerosis and HAM/TSP programs for autoimmune neurodegenerative diseases and with Yale University to advance our Type 1 Diabetes program are examples of partnerships we will establish to help drive this technology forward for patients.

- ***Leverage partnerships to drive new product development in virally mediated infectious disease.*** In addition to autoimmune disorders, we believe that there may be significant opportunities to address virally mediated infectious diseases via either the AIM ACT or AIM INJ modality. We also believe that the AIM technology may be applicable to the treatment of, and preparation for, future virally mediated epidemics and pandemics. While we believe that our AIM technology platform is well-suited to address these new therapeutic opportunities, we expect that we would partner with experienced biopharmaceutical companies with deep capabilities in these areas to advance new therapies in these potential indications. Our collaborations with the NIH in Multiple Sclerosis and HAM/TSP and Yale University in Type 1 Diabetes are examples of partnerships we will establish to help drive this technology forward for patients.

While we intend to establish our own internal capabilities to develop and commercialize our product candidates, we will also explore strategic collaborations or partnerships that may accelerate our development timelines, broaden the therapeutic reach of our AIM technology platforms and maximize the full potential of both the AIM ACT and AIM INJ modalities.

Our Clinical-Stage Product Candidates

We have two programs in clinical trials: NEXI-001 for AML patients and NEXI-002 for MM patients, with enrollment in both currently paused due to resource constraints.

NEXI-001

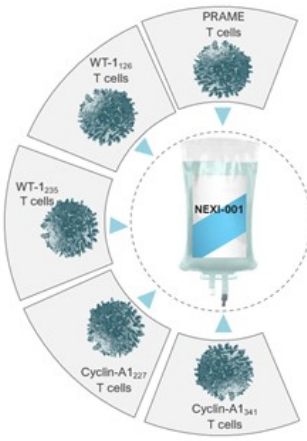
NEXI-001 is an allogeneic cell therapy in Phase I/II development for the treatment of patients with AML who have relapsed disease after receiving allo-HSCT. Allo-HSCT is currently the only therapeutic procedure with established curative potential for intermediate and high-risk AML patients. However, of the approximately 20,000 patients diagnosed with AML in the United States in 2019, approximately 50% were young or healthy enough to qualify for allo-HSCT. Of those patients who do receive allo-HSCT, fewer than half are cured. Patients who relapse after allo-HSCT face a dismal prognosis and are left with limited treatment options. Most will succumb to their disease within one year of relapse and the two-year survival rate is less than 15%. Many of these patients fail to respond to further salvage treatments with an even worse prognosis.

Treatment Paradigm for AML

While there are currently no approved therapies for this relapsed patient population, donor lymphocyte infusion, or DLI, is employed as the standard-of-care treatment. DLI is a procedure in which non-selected and non-disease specific T cells are collected from an AML patient's original stem cell donor by apheresis. The T cells are then infused directly into the AML patient with the hope that some populations of the infused T cells will recognize and kill the patient's leukemia cells, directing a graft versus leukemia, or GvL, effect. Unfortunately, this blunt approach works in only approximately 15% to 20% of patients. Making matters worse, approximately 50% to 60% of patients that receive DLI therapy experience life-threatening toxicities associated with non-leukemia specific T cells from the donor attacking healthy cells in the patient, a condition referred to as Graft Versus Host Disease, or GvHD. Currently, there is no way for a treating physician to "de-couple" the benefits of GvL from the toxicities of GvHD. They are not able to separate the "good" T cells from the "bad." Because each NEXI-001 infusion

contains high proportions of T cells that are directed to specifically recognize and attack only a patient's leukemia cells and are comprised of very few T cell subtypes capable of eliciting a GvHD response, we believe therapy with NEXI-001 offers the potential to enhance the benefits of GvL while significantly reducing the risk of GvHD.

Our AIM technology is used to produce the NEXI-001 product candidate. As illustrated in the graphic below, AIM nanoparticles are loaded with five AML-specific peptides from the *WT 1, PRAME and Cyclin A1 antigens*, which are used to enrich and expand AML-specific T cells. These AML-specific T cells recognize and attack these specific antigen peptide targets, which are commonly over-expressed on both leukemic blasts and leukemic stem cells.



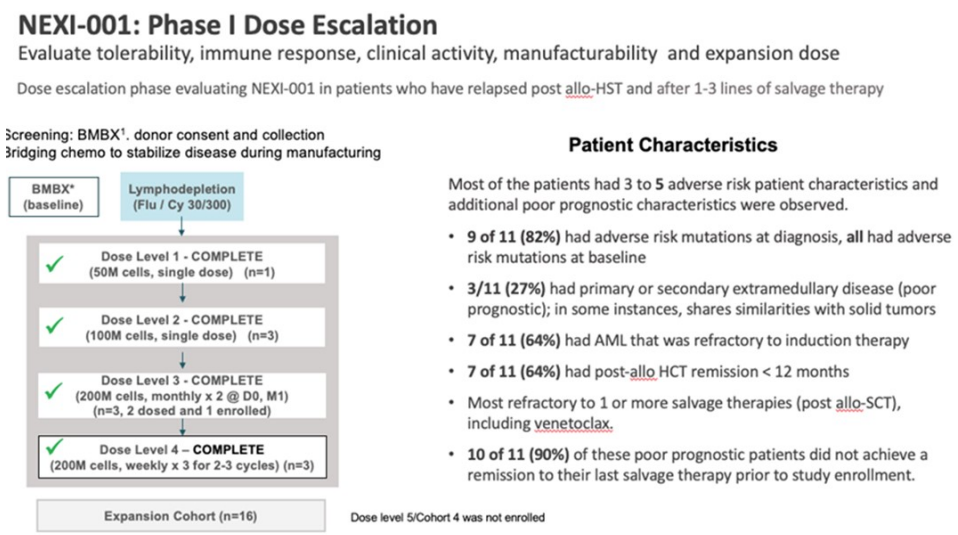
The T cells in NEXI-001 are designed to be highly potent and highly selective in their ability to distinguish leukemia cells from healthy cells, and to contain key T cell subtypes that promote immunologic memory and long-term T cell persistence. We believe this combination of attributes has the potential to deliver deep and durable clinical responses for these AML patients.

Phase I/II Clinical Trial Design

Our clinical trial with NEXI-001 is a prospective, multi-center, open-label, single-arm, dose-escalating Phase I/II trial that aims to enroll between 22 and 26 patients. The primary objective is to assess the safety and tolerability of a single infusion of NEXI-001 T cells in patients with AML who have either minimum residual disease, or MRD, or morphologically detectable disease after an HLA-matched allo-HSCT. As a practical point, the NEXI-001 trial enrolls patients who have not achieved a remission to salvage therapy after relapse following the transplant. Secondary objectives include signals of immunologic responses and preliminary anti-tumor activity, including evaluations of the following clinical endpoints: overall response rate, or ORR, which includes complete response, or CR, progression free survival, or PFS, and overall survival, or OS. Additional analysis will assess the *in vivo* persistence, proliferation, functionality and TCR repertoire of NEXI-001 T cells as measured in blood and bone marrow samples. Our clinical endpoints have been recognized as appropriate measurements of safety and clinical response.

This trial consists of two parts. The initial safety evaluation phase assesses the safety and tolerability of a single infusion of NEXI-001 at escalating dose levels. In the second part of the trial, the dose expansion phase, investigators further characterize safety and will also evaluate the initial efficacy of NEXI-001 T cells at the dose established in the safety evaluation phase. Once the recommended dose and regimen have been determined, evaluations of safety, tolerability and initial clinical response will become the objectives of the second part of the trial, the expansion phase. We are currently in the safety evaluation phase of the trial. The City of Hope Cancer Center is the lead clinical trial site for this trial, with additional trial sites at the Dana Farber Cancer Center, the M.D. Anderson Cancer Center, the Memorial Sloan Kettering Cancer Center, the Karmanos Cancer Institute, the Ohio State University Comprehensive Cancer Center, and the Advent Hospital in Orlando, Florida.

The schema for this trial (and current enrollment) is shown below:



Preliminary Data from the Phase I/II Clinical Trial

We have completed enrollment and dosing in the dose escalation phase, with a total enrollment of 11 patients. We have previously reported data from six patients across Dose Level 1, Dose Level 2 and Dose Level 3 safety cohorts to date and Dose Level 4 has been completed. Two additional patients were reported at ASCO in 2023. One reported patient (Dose Level 3, 200M single dose) maintained a complete response up to 6 months. The second patient reported (Dose Level 4 200M T cells, Day 0, Day 8, Day 15) presented with extramedullary disease with an observed clinical response up to 3 months. Since ASCO, additional data has been shared for these two patients that maintained response up to 9 months and 10 months respectively. Importantly, investigators have observed a dose response. Data analyses are being finalized and will be shared at an appropriate scientific forum.

Each of these patients has been closely monitored for safety and early signs of clinical activity. In addition, biomarkers were analyzed to assess early signs of immunologic response; clinical lab reports and patient charts were used to measure myeloid activity (neutrophils counts, platelet counts, Red Blood Cell counts, transfusion burden); and validated clinical endpoints were incorporated to measure early signs of clinical activity. It is important to note that we are early in the safety evaluation and dose-finding part of the Phase I/II trial, and that the results reported here represent data from the 11 patients in the dose escalation safety phase and are not statistically significant.

Safety and tolerability. The NEXI-001 therapy has been well tolerated without dose limiting toxicities, observed after a across all doses evaluated. This includes no $\geq$ grade 3 cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or ICANS, or infusion-related reactions, or IRRs at any Grade Level (Grade 1-4). One Grade 3 and one Grade 1 GvHD was observed in patients with a history of GvHD and resolved within 72 hours.

Immunological responses. In the first six patients, treated we have observed initial indicators of immunologic response after the infusion of NEXI-001 T cells, including (i) early lymphocyte reconstitution to baseline levels after administration of lymphodepleting therapy with rapid and robust recovery of the CD4+ T cell compartment; (ii) the proliferation and persistence of NEXI-001 antigen-specific T cells as measured by multimer-staining of peripheral blood when adequate samples were available for analysis; (iii) clonal expansion and persistence of NEXI-001 T cells in both peripheral blood and bone marrow as measured by TCR sequencing when data was available; and (iv) the presence of T cell subtypes that support anti-tumor activity, T cell proliferation, self-renewal and long-term persistence as measured by phenotype staining of NEXI-001 antigen-specific T cells in peripheral blood over time when adequate samples were available for analysis. It is important to note that we are early in the safety evaluation and dose-finding part of the Phase I/II trial, and that these results are not statistically significant.

Patient Characteristics

NEXI-001: 64% have 3-5 adverse risk characteristics which had increased at baseline – in addition to poor prognostic characteristics

	Cycles	PT ID	Age/ Gender	Response to induction chemo (CR)	Response to chemo (CR) prior to infusion	SCT to relapse (month)	Adverse cytogenetics at Initial Dx	Hx of GvHD	Extra-medullary disease
1 50M	1		65 M	Refractory	Refractory	5	RUNX1/ ASXL1-	Skin; steroid inhaler	CNS disease
Cohort 1 100M /cycle	1	1-003	40 M	Refractory	Refractory	78	No abnormal blasts	Eye, mouth	Retroperitoneal Myeloid sarcoma
	1	1-004	72 F	Refractory	Refractory	3	FLT3-ITD-	Unknown	No
	1	1-006	43 M	Refractory	Refractory	10	P53 & complex karyotype	Skin, mouth, eyes, GI & joints	No
Cohort 2 200M / cycle	2	1-005	23 M	Refractory	Refractory	25	Monosomy 7	Skin	No
	2	5-005	68 M	Responded	Refractory	4	RUNX1/ ASXL1	GvHD (type UNK)	No
	1	1-018	46 M	Refractory	Refractory	3	GATA2	Skin & liver, on steroids	No
	1	1-017	55 F	Responded	Responded	24	RUNX1	Skin, mouth, eyes, liver	No
Cohort 3 DL4 600M /cycle x 2	1	3-004	46 F	Refractory	Refractory	9	DNMT3A	Skin, liver, GI Chronic Steroids (prior/during)	No
	1	1-026	76 F	Responded	Refractory	19	RUNX1/ DNMT3A	Eyes, mouth Steroids (use UNK)	Pericardial and pleural effusions (+ cytology)
	1	1-027	21 M	Responded	Refractory	6	KMT2A	Skin	No

Summary of Patient Experience

As discussed above, we have previously reported clinical data in six patients for NEXI-001's initial clinical trial. Here we provide baseline characteristics of all 11 patients in the safety phase of the study, with a dose-ascending plan. The first patient received a single dose of 50M T cells, the next three patients received a single dose of 100M T cells. Two patients received one dose of 200M cells, and two patients received 200M cells at Day 0 and Day 30 for a total of 400M cells. Dose Level 4 included patients that received 200M cells administered weekly for three weeks (Day 0, Day 8, Day 15) for a total of 600M cells.

The data from the initial dose levels reported to date are encouraging and supports progression to the expansion phase at this last dose and include a second cycle. Additional dose levels are under consideration. Specifically, we have observed:

NEXI-001 is well-tolerated.

- No DLT's were observed, no deaths and no discontinuation to TEAE's. One Grade 3 and one Grade 1 GvHD was reported in patients with a history of GvHD, which resolved within 72 hours. Two cases of transient CRS were reported which resolved.

NEXI-001 generates a robust immune response across all dose levels reported to date:

Rapid recovery of absolute lymphocyte counts (ALC) following the pre-therapy lympho depleting chemotherapy regimen including reconstitution of both CD8+ and CD4+ T cell subtypes, despite the fact that NEXI-001 contains CD8+ T cells only. Expansion and persistence of antigen-specific T cells in both the peripheral blood and bone marrow.

- The phenotypes of the antigen-specific T cells in the NEXI-001 product candidate, including stem-cell-like memory and central memory T cell populations, are maintained in blood and the bone marrow over time.

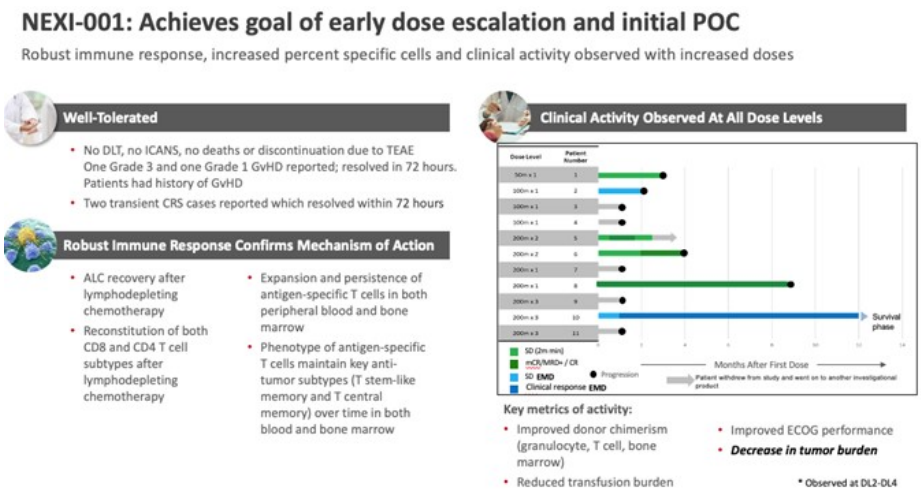
Signals of NEXI-001 of clinical activity across all dose levels reported to date:

Investigators have observed some or all of the following:

- Evidence of dose response.

- Evidence of marrow recovery based on improved donor chimerism (i.e., granulocytes, T cells, bone marrow) and where relevant, reduced transfusion burden.
- Improved ECOG performance.
- Evidence of reduced tumor burden based on decreases in peripheral blasts and a decrease in bone marrow blasts.

The following chart summarizes the preliminary clinical experience of the patients at the various dosing levels:



As described above, we have completed enrollment and dosing of patients in Dose Level 4. Four out of seven patients in the last 2 dose levels achieved Best Status / Best Response of at least morphological CR (3 months up to 9+ months). Investigators observed a dose response with an acceptable tolerability profile. Observations from this safety phase (e.g. patient baseline characteristics) will be applied to any future expansion or new studies pending resources. As illustration, a patient in Dose Level 4 was enrolled with ongoing chronic steroid dosing, a known immunosuppressive agent and another patient in Dose Level 4 presented with >90% blasts in *both* blood and marrow. Though paused at this time, enrollment in any future study will require a steroid washout period and establish reasonable limits on high disease burden. Based on the tolerability observed, a second dose cycle of Dose Level 4 is proposed should the program be resourced and continued. We are still collecting data on these patients and expect to share this data at an appropriate scientific forum. At this time, further enrollment is paused due to resource constraints.

NEXI-002

NEXI-002 is an autologous cell therapy in Phase I/II clinical development to treat patients with relapsed and/or refractory MM who have failed at least three prior lines of therapy. We have currently paused enrollment in the expansion phase of the trial due to resource constraints. MM accounts for around 10% to 15% of all hematologic malignancies and primarily affects older individuals, with approximately 32,000 new cases a year in the United States. While significant progress has been made in the treatment of MM, there is currently no cure for the condition.

Treatment Paradigm for MM

There are currently several T cell therapies under clinical investigation for this patient population. Among them, anti-B-cell maturation antigen, or BCMA, transduced CAR T therapies have demonstrated early and impressive initial clinical results across multiple Phase II/III clinical trials, with objective responses rates, or ORR, greater than 90% in patients reported within some individual trials, though tumor escape and relapse remains a significant challenge.

CAR T therapy, by design, uses an antibody to target a single protein, such as BCMA, expressed on the surface of a plasma cell. These surface proteins are not critical to the survival of the plasma cell and can be downregulated when under immune pressure, such as from the CAR T cellular therapy. As a result, the tumor cell can avoid detection by the CAR T cell in a process known as tumor escape. We also believe that a primary driver of tumor relapse following CAR T therapy is the loss of CAR T cells from a patient's body: the CAR T cells do not persist. Due to the way CAR T cells are manufactured, they contain highly potent T cells, but do not contain the natural T cell subtypes that support self-renewal, immunologic memory and long-term persistence. When the CAR T cells die out, the cancer can relapse.

NEXI-002 was designed to address these emerging limitations of CAR T therapy.

- *Tumor escape*. Each infusion of NEXI-002 contains populations of T cells directed to recognize and attack multiple antigen targets on each malignant plasma cell, as shown in the figure below. These targets represent a combination of cell surface antigen proteins, such as *CS-1 and CD138, and endogenously presented survival antigen proteins, such as WT-1 and NY-ESO*. We believe that by targeting multiple antigen proteins that are over-expressed on each malignant plasma cell, some of which are necessary for tumor cell survival, NEXI-002 has the potential to effectively address tumor escape as an immune evasion mechanism.

- *T cell persistence and tumor relapse.* The AIM technology has been optimized to consistently produce product candidates that contain T cell subtypes that support anti-tumor potency, self-renewal, immunologic memory and long-term T cell persistence. We believe the combination of these T cell characteristics has the potential to effectively address disease relapse due to short-term T cell survival.

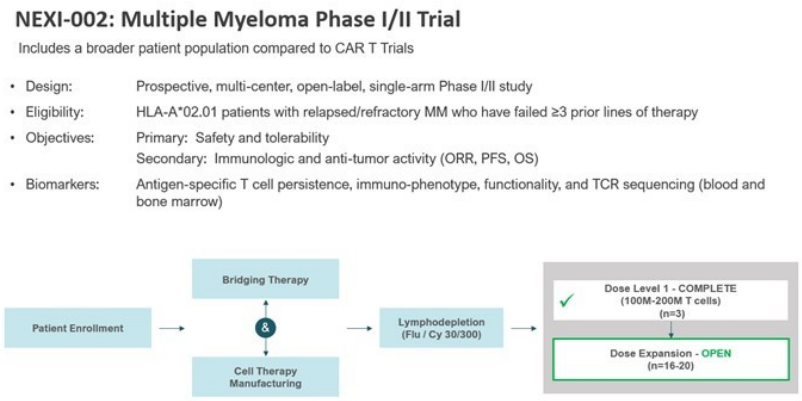
When taken together, we believe these attributes of NEXI-002 give it the potential to improve the durability of clinical responses observed with current approved therapies and improve the toxicity profile reported to date when using these genetically engineered T cell modalities.

As with NEXI-001, our AIM technology is used to produce each NEXI-002 infusion. AIM nanoparticles loaded with MM-specific antigen peptides, enriched and expanded by the E+E system, generate populations of T cells that are directed to recognize and attack the specific antigen targets, as illustrated in the graphic below.

The T cells in each NEXI-002 infusion are designed to be highly potent and highly selective in their ability to distinguish malignant plasma cells from healthy plasma cells, and to contain key T cell subtypes that promote anti-tumor potency, immunologic memory and long-term T cell persistence. We believe this combination of attributes has the potential to deliver deep and durable clinical responses for MM patients who have failed at least three lines of prior therapy.

Ph*ase I/II Clinical Trial Design*

Our clinical trial with NEXI-002 is a prospective, multi-center, open-label, single-arm, dose-escalating Phase I/II clinical trial with planned enrollment between 19 and 23 patients. The initial safety evaluation phase assessed the safety and tolerability of a single infusion of NEXI-002 within a single dose range. In the second part of the trial, the expansion phase, investigators will further define safety and will also evaluate the initial efficacy of each product candidate at the dose established in the safety evaluation phase. The trial's primary objective is to assess the safety and tolerability of a single infusion of NEXI-002 T cells in patients with MM who have failed at least three prior lines of therapy. Secondary objectives include signals of anti-tumor activity, ORR (which includes CR), OS and PFS. Additional biomarker analyses will assess the *in vivo* persistence, proliferation, functionality and TCR repertoire of NEXI-002 T cells as measured in blood and bone marrow samples. Our clinical endpoints have been recognized as appropriate measurements of safety and clinical response. The clinical trial sites include City of Hope Cancer Center, the M.D. Anderson Cancer Center, the Memorial Sloan Kettering Cancer Center, the Karmanos Cancer Institute, the Ohio State University Comprehensive Cancer Center, the Dana Farber Cancer Center, and the Advent Hospital in Orlando, Florida.



Preliminary Data from the Phase I/II Clinical Trial

Enrollment in this clinical trial has been paused with seven patients enrolled and dosed. We report data on a total of six patients, of which three patients were treated in the Safety Evaluation Phase and three patients were treated in the Expansion Phase. The remaining data will be shared in an appropriate scientific forum.

Safety and tolerability. The NEXI-002 therapy has been well tolerated without dose limiting toxicities observed after a single infusion of NEXI-002 T. This includes no $\geq$ grade 3 cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or ICANS, or infusion-related reactions, or IRRs at any Grade Level (Grade 1-4).

Immunological responses. TCR sequencing showed that NEXI-002 product contains T cell clones that were undetectable in the peripheral blood of patients at baseline. The product contains CD8+ antigen specific T cells with memory phenotypes. Upon dosing, patients saw a rapid lymphocyte recovery with reconstitution of both CD4 and CD8+ T cells. NEXI-002 cells were detected in the peripheral blood and bone marrow and persist and proliferate over time. The quality and functionality of the NEXI-002 T cells is comparable to those expanded from healthy donors. Strategies to yield higher product doses have been implemented as the trial progresses and the NEXI-002 protocol has been amended to include patients with smoldering multiple myeloma (an early stage of multiple myeloma).

Manufacturing. Strategies to yield higher product doses have been successfully implemented to support dose escalation in heavily pre-treated patients.

Lower burden of disease. Patients enrolled in the study had an average of eight prior lines of therapy. Based on initial safety data, the NEXI-002 protocol has been amended to include patients with smoldering multiple myeloma (an early stage of multiple myeloma).

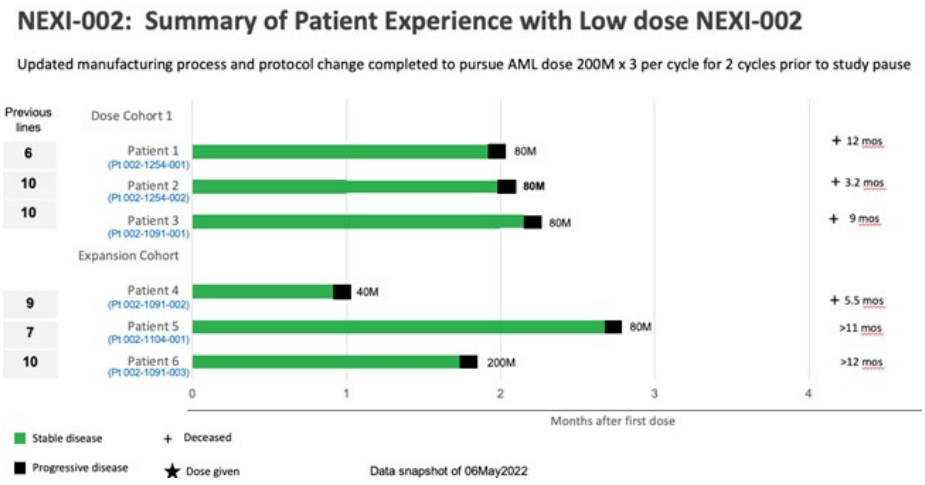
Patient Characteristics

NEXI-002-01: RRMM Patient Characteristics

Average 8 prior lines including ASCT and CAR-T therapies

Cohort	Dose	Patient	Age	Gender	# prior lines before to bridging/dose	M-protein	FISH	Remarks
Safety Evaluation	80M	002-1254-001	59	M	6	IgGλ	t(11;14)	20% plasma cells in BM
	80M	002-1254-002	55	M	10	IgGκ	Gain of 9, 11, 15	95% plasma cells in BM; multiple LBLs
	80M	002-1091-001	39	M	10	K light chain	No abnormalities	EM masses; multiple LBLs
Expansion	40M	002-1091-002	52	F	9	K light chain	No abnormalities	Multiple LBLs
	80M	002-1104-001	56	F	7 (includes 3 prior ASCTs)	IgGλ	Complex abnormalities	50% plasma cells in BM; multiple LBLs
	200M (900M NEXI-002 yield)	002-1091-003	50	M	10 (includes an ASCT & 2 CAR-T therapies)	λ light chain	Normal Karyotype	60% cellularity No increase in plasma cells

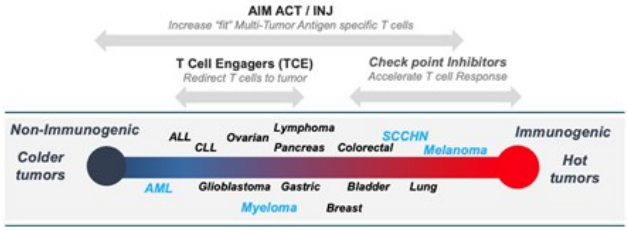
Summary of Patient Experience



Future Opportunities

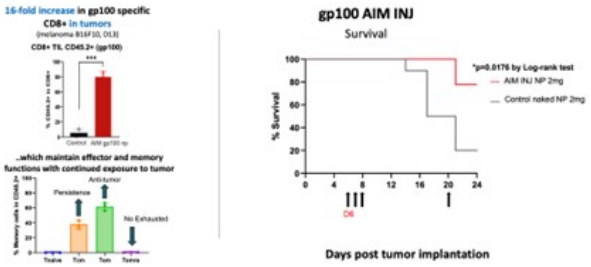
Moving forward, our strategy is to focus on the development of the AIM INJ modality, with the expectation that we will be able to advance it through IND approval and into a Phase I/II clinical trial, resources permitting. We believe the data we have already collected is validating of the AIM platform's mechanism, which gives us a favorable risk profile as we seek to establish the technology in solid tumors, infectious diseases and autoimmune disorders. We have generated a significant body of combined clinical and non-clinical data to support the AIM nanoparticle-based approach, which we use to prioritize our clinical development efforts and to identify potential disease areas and indications to pursue.

- *Create new cancer treatment paradigms in tumor types across a range of immunogenicities.*

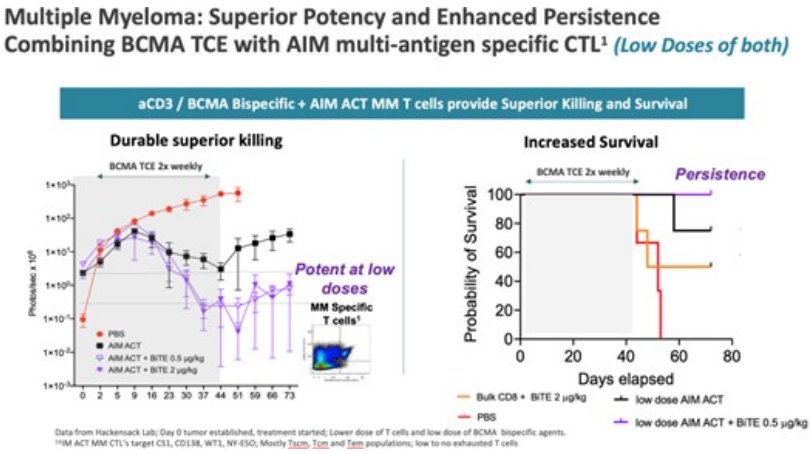


- *Solid Tumors*. Our IND for NEXI-003 in HPV-associated malignancies has been accepted by the FDA, but the planned Phase I/II clinical trial has been paused due to resource constraints. HPV-associated malignancies remain a disease area of high interest for the AIM INJ platform, and there are many more opportunities for the AIM technology in the solid tumor space. The scientific community has identified, robustly characterized and clinically evaluated over 75 specific antigen targets (including intracellular and surface antigens as well as shared common neo-antigen epitopes) across multiple solid tumor types, and we plan to use this data to inform our next wave of multi-antigen targeted product development in oncology. Additionally, combinations of multi-antigen specific AIM therapeutics with CPI's remain a potential IO/IO breakthrough. Our ACT T cells have demonstrated superior anti-tumor effect, survival and T cell persistence in melanoma models. Initial pre-clinical INJ data demonstrate persistence of "fit" specific T cells and significant survival in an established tumor model. Dose regimen optimization is ongoing.

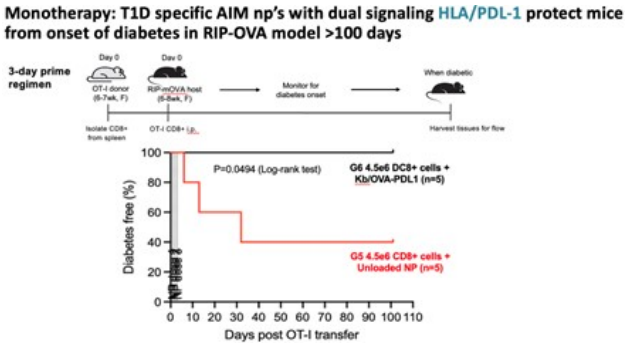
Gp100 AIM INJ induces "fit" antigen-specific T cells that penetrate tumor and persist which extends the overall survival in B16 melanoma model



- *Hematology (Blood Cancers)*. The AIM multi-antigen approach has the potential to pursue a broader set of targets to address escape and durability. Combined, early clinical data is consistent with pre-clinical results demonstrating antigen specific cells proliferate, traffic and persist at the site of tumor. Additionally, opportunity exists to move into earlier disease to halt progression. Recent publications have associated T cell fitness as a predictor of response in MM. Pre-clinical data supports this concept and suggests a novel combination of low dose AIM nanoparticle expanded T cells with low dose bispecific T cell engager (e.g., CD3/BCMA, CD3/Flt-3) with the potential to achieve synergistic, superior potency and durability in tumors where the tumor microenvironment is more immunosuppressive.



- *Autoimmune Disorders*. We believe that our AIM technology will enable us to target autoimmune conditions using either the AIM ACT or AIM INJ modality. For most autoimmune disorders like Type 1 Diabetes (T1D), autoreactive (or self-destructive) T cells become the cells targeted for therapeutic intervention. AIM nanoparticle Signal 1 protein (MHC) can be loaded with antigen peptides that recognize targeted autoreactive T cells and is combined with a different Signal 2 (PDL1-Ig or aFas) to deliver a suppressive or apoptotic signal that either tolerizes or eliminates the disease-causing T cells. No off-target effect has been observed pre-clinical evaluation. In a Type I diabetes study (Dr. Herald's lab, Yale), disease specific INJ prevented development of disease for >100 days (length of study) vs control in a murine model.



- In conditions like multiple sclerosis, or MS, the Epstein-Barr virus, or EBV, plays a critical role in mediating the disease process. Eliminating EBV-infected cells with EBV-specific T cells has been shown by others to impact disease progression for patients with Primary Progressive MS and could be done using the AIM ACT approach. We believe that EBV-specific AIM ACT or AIM INJ product candidates can be developed for clinical evaluation in various forms of MS. While initial pre-clinical development is focused on an MHC Class I approach, we have developed Class II nanoparticles that unlocks significant potential for additional autoimmune indications.

- *Infectious Diseases*. We believe that there may be significant opportunities to address other viral-mediated diseases using the AIM platform to develop either AIM ACT or AIM INJ product candidates. We also believe that the AIM technology may offer a novel approach to the rapid treatment of, and preparation for, future viral-epidemics and pandemics.

- *Expanding to new HLA allele subtype populations*. We are also developing additional HLA allele subtypes. NEXI-001 and NEXI-002 currently use the HLA-A2 allele, which is the most prevalent allele in the North American population. However, the additional HLA subtypes we plan to develop, including HLA-A1, HLA-A3, HLA-A11, HLA-A24 and HLA-B7, would broaden the patient eligibility of future product candidates. We believe the modular AIM platform will facilitate the rapid development of nanoparticles that exchange the current HLA-A2 for new HLA subtypes, which will then be used for all AIM product candidates in development.

- *Advance our AIM based functional Target Validation method.* We have designed a multiplex approach to functionally assess immune responses as a new dimension for research target evaluation and TCR deconvolution.

In addition, we continually survey the scientific and industry landscape for opportunities to license, partner or acquire technologies that may help us advance current or new T cell therapies for the benefit of patients.

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused commercial organization in the United States to market, sell and distribute our products. We believe that such an organization can efficiently address the community of hematologists and oncologists who are the key specialists treating the patient populations for which our most advanced product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties to support any of our product candidates that obtain marketing approval.

Given our potential to generate novel product candidates with potential to address a wide variety of cancers, autoimmune and infectious diseases, we may also consider opportunistically entering into strategic partnerships focused on certain targets, product candidates, disease areas or geographies. These collaborations could advance and accelerate our current clinical and platform development programs in ways that could maximize product availability and value creation.

Competition

We are initially developing product candidates to address hematological malignancies, which will be followed by an expansion into solid tumors, autoimmune disorders and infectious diseases. Accordingly, we may face competitors from multiple biotechnology or biopharmaceutical companies, many of which have access to greater resources, technical expertise and broader collaborations that could result in faster development, exclusive access to novel enabling technologies, biomarker-based differentiation or commercialization. These competitors also compete for recruiting and retaining talent in critical areas of research, development, manufacturing, regulatory and commercial functions. If our current or future product candidates do not offer sustainable advantages over competing products, we may not be able to successfully compete against current and future competitors.

The field of immuno-oncology is rapidly evolving, and we expect to compete with companies developing other approaches to direct T cell function. These include but are not limited to, the following modalities.

Genetically Engineered T Cells

These include both CAR-T and TCR engineered cell therapies being developed as treatments for MM and AML. CAR-T cell therapies generally target single cell surface antigen proteins and are mostly limited to blood tumors, including products and product candidates being developed at companies such as Bristol-Myers Squibb Company, Novartis AG, Gilead Sciences, Inc., Fate Therapeutics, Inc. and Mustang Bio, Inc. We also expect to compete with TCR engineered cell therapies, which employ high affinity TCR's against a single endogenously presented antigen peptide, including products and product candidates being developed by companies such as Adaptimmune Therapeutics plc, GlaxoSmithKline plc, Gilead Sciences, Inc. and Immatics N.V. More recently, select CAR-T cell companies have transitioned to autoimmune B cell diseases such as systemic lupus erythematosus (Cabaletta).

Non-engineered Endogenous T Cells

These are cell therapy approaches that employ the *ex vivo* activation and expansion of non-genetically engineered endogenous T cells. TIL therapies are an approach that requires harvesting patient tumors and expanding these cells as a final product. Amtagvi (Iovance Biotherapeutics, Inc) is the first approved TIL therapy for solid tumors with a lead indication of melanoma. Future options that increase antigen specificity, T cell fitness offer significant potential benefit. Additional approaches use antigen presenting cell, or APC, based systems, typically as *ex vivo* activation and expansion systems, are being

developed by companies such as Atara Biotherapeutics, Inc. and Marker Therapeutics, Inc. These approaches rely on the host immune cells to provide instructions to T cells.

Cancer Vaccines

Similar to APC based systems described above, injectable cancer vaccine approaches (e.g. mRNA) rely on host antigen presenting cells as intermediaries to process and present specific signals that direct a targeted T cell function, including products and product candidates being developed at companies like BioNTech SE and Moderna, Inc. Recent success in the adjuvant setting in combination with CPI to prevent progression in encouraging. Novel approaches that can be used beyond the adjuvant setting are needed.

Approaches for Autoimmune Disorders

Recently, cell therapy companies have transitioned their CAR-T cell programs into lupus, a well-established B cell driven autoimmune disease. (Novartis, BMS, Karverna, Atara, Gracell). Additional approaches in development focus on establishing tolerance through T regulatory mechanisms. Most clinical approaches expand non-antigen specific regulatory T cells (T_{reg}) to provide broad immune regulation. Other modalities rely on host antigen presenting cells for the induction T regulatory activity and tolerance. Yield and control of antigen specificity remains a challenge. (Quell, Sangamo, Lisata).

Antibody Platforms

These modalities employ modified antibodies to redirect T cell function and include bispecific T cell engagers, or BiTEs, and dual-affinity re-targeting proteins, or DARTs, including products and product candidates being developed at companies like Amgen Inc., GlaxoSmithKline plc, Johnson & Johnson and MacroGenics, Inc.

Our competitors may obtain regulatory approval for their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products. These competitors may also be more successful in manufacturing and marketing their products.

Johns Hopkins License Agreement

In June 2011, we entered into an exclusive license agreement with Johns Hopkins, which was subsequently amended and then superseded in January 2017 by an amended and restated exclusive license agreement, which we refer to as the A&R Johns Hopkins License Agreement. Pursuant to the A&R Johns Hopkins License Agreement, we have (i) an exclusive license to make, have made, use, import, offer for sale and sell artificial antigen presenting cells (AIM nanoparticles) covered by patent rights owned by Johns Hopkins in therapeutic, diagnostic and non-clinical fields, (ii) an exclusive license to make have made, use, import, offer for sale and sell fusion proteins covered by patent rights owned by Johns Hopkins in the therapeutic field, (iii) a non-exclusive license to make, have made, use, import, offer for sale and sell fusion proteins covered by patent rights owned by Johns Hopkins in diagnostic and non-clinical fields and (iv) a non-exclusive right to use Johns Hopkins's know-how to develop, make, have made and sell products covered by patent rights owned by Johns Hopkins and to develop and provide services covered by the patent rights owned by Johns Hopkins. The rights licensed to us are worldwide and include the right to grant sublicenses.

Johns Hopkins retains rights to practice the patent rights and know-how for itself and other non-profit academic and non-profit research institutions for any non-profit, non-commercial research or other non-commercial purpose. The United States government may have a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States throughout the world the inventions described in the patent rights owned by Johns Hopkins that were supported by federal funding. We may be obligated to manufacture the products sold or used in the United States that are covered by patent rights supported by federal funding substantially in the United States.

Under the terms of the 2011 license agreement and the A&R Johns Hopkins License Agreement, Johns Hopkins was entitled to an up-front license fee of $155,000 and we issued them 26,918 shares of our common stock. Johns Hopkins was also entitled to milestone fees of $75,000 in connection with clinical trial milestones. For the first licensed product or licensed service in the therapeutic field, we may be required to pay Johns Hopkins additional aggregate milestone fees of $1.6 million for clinical and regulatory milestone fees. We may be required to pay Johns Hopkins reduced milestone fees for the second and third licensed products or licensed services in the therapeutic field in connection with clinical and regulatory milestones. In the diagnostic field, we may be required to pay Johns Hopkins aggregate milestone fees of $400,000 for the first licensed product or licensed service and reduced milestone fees for the second and third licensed products or licensed services. We may be required to pay Johns Hopkins aggregate milestone fees of $100,000 for commercial milestones for the first licensed product or

licensed service in the non-clinical field. In total, we may be required to pay Johns Hopkins additional milestone fees of up to $4.2 million for all clinical, regulatory and commercial milestones for all licensed products or licensed services in the therapeutic field, the diagnostic field and the non-clinical field. We may also be required to pay royalties in the low to upper single digits on net sales of licensed products and licensed services in the therapeutic field, diagnostic field and non-clinical field that are covered by the patent rights owned by Johns Hopkins or use know-how of Johns Hopkins. We are required to make minimum annual royalty payments of $100,000 to Johns Hopkins for the remainder of the term of the A&R Johns Hopkins License Agreement; the amount of the minimum annual royalty payment started in the low five figures in the first year of the agreement and increased to $100,000 in the third year of the agreement and for each subsequent year of the agreement. We may also be required to pay Johns Hopkins a low double digit percentage, not to exceed 15%, of any non-royalty sublicense consideration we receive. We are also required to use commercially reasonable efforts to meet certain clinical and technical diligence milestones.

We must make minimum royalty payments, which began upon the 4th anniversary of the agreement and upon every anniversary thereafter during the term of the agreement, which offset future royalties per above owed to John Hopkins.

In the event Johns Hopkins or another party provides us with clinical or other evidence demonstrating the practicality of a particular market or use within the therapeutic, diagnostic or non-clinical fields that we are not developing or commercializing, we are required to use commercially reasonable efforts to start development or attempt to sublicense to a suitable third party for that particular market or use. If we fail to use commercially reasonable efforts to commence development or do not grant a sublicense to a suitable third party, all rights to that particular use will revert back to Johns Hopkins at no cost and Johns Hopkins will be able to license that particular use to third parties. We are not required to cause development of any licensed product or licensed service for a particular market or use if we reasonably demonstrate to Johns Hopkins that developing such licensed products or licensed services or granting a sublicense for such market or use would a have a potentially adverse commercial effect upon licensed products or licensed services being developed or sold by us, our affiliates or our existing sublicensees.

Unless terminated earlier in accordance with the agreement, the A&R Johns Hopkins License Agreement and the royalty obligations thereunder will continue on a licensed product-by-licensed product or licensed service-by-licensed service and country-by-country basis until the expiration date of the last-to-expire patent or, if no patents issue, until the tenth anniversary of the agreement, at which time the licenses will become fully paid up and royalty-free.

We or Johns Hopkins may terminate the A&R Johns Hopkins License Agreement if the other party files for insolvency or if there is an uncured breach of obligations or failure to perform by the other party. We may terminate the A&R Johns Hopkins License Agreement upon giving Johns Hopkins 90 days' written notice.

Zephyr Joint Research Agreement

In March 2022, we entered into a Joint Research Agreement, or JRA, with Zephyr AI, Inc., or Zephyr, focused on the joint collaboration, identification and validation of certain targets in order to facilitate further research, development and potential commercialization of immunotherapies. Pursuant to the JRA, Zephyr will identify suitable antigens or combinations thereof for validation and testing by NexImmune. The Joint Steering Committee provided for by the JRA, or the JSC, will then determine which identified candidates shall be subject to further analysis. We will validate which, if any, of the identified antigens are suitable for T-cell engagement and killing function, which antigens are referred to as the Final Candidates. The JSC will make a good-faith determination as to whether the data supports the further IND-targeted development by us of any of the Final Candidates. We and Zephyr will jointly own any Final Candidates, including the intellectual property related thereto. Each of the company and Zephyr shall be responsible for payment of their own respective costs and expenses in connection with the performance of their respective obligations under the JRA. If a Final Candidate is to be further developed, then we and Zephyr shall engage in good-faith negotiations to agree on the terms and conditions of an agreement with respect to the further development and commercialization of such Final Candidate. If such an agreement is not executed within the prescribed negotiation period, then neither we nor Zephyr may further develop such Final Candidate.

Each of the company and Zephyr can terminate the JRA (i) for any reason upon 90 days' written notice, and (ii) upon the other's breach or default of any of the terms and conditions thereof, subject to 30 days' notice and cure period. Absent early termination or mutual extension, the JRA shall terminate two (2) years after the effective date. As of March 16, 2024, neither party extended the JRA and the JRA is terminated.

Intellectual Property

We believe that our patents and patent applications, and other proprietary rights, that we own or control through licensing, are important to our business and competitive position. In addition to patents, we rely on trade secrets, know-how, and continuing technological innovations to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants, advisors and other parties. Our success will depend in part on our ability, and the ability of our licensor, to obtain, maintain (including making periodic filings and payments) and enforce our patents, including those patents and applications to which we have exclusive rights.

We own or have exclusively licensed seven issued United States patents and eight pending patent applications for the United States (including U.S. provisional applications). We also have 80 issued or allowed foreign patents and 46 pending foreign patent applications (including pending PCT Applications) intended to protect the intellectual property underlying our technology. In addition to the United States, we have patents issued or applications pending in Australia, Brazil, Canada, China, Europe (EPO), Hong Kong, India, Israel, Japan, South Korea, Mexico, Russian Federation, and Singapore. Our patent applications describe and claim certain features of our technologies, including our T cell activation and expansion platform, our cell therapy product candidates, and our drug candidates based on injectable artificial antigen presenting cells. We currently control issued patents in the United States, Australia, Canada, China, Europe (through the European Patent Convention), Hong Kong, India, Israel, Japan, Mexico, Singapore, South Korea, and Russian Federation, which relate to the technology for generating our cell therapy products (NEXI-001 and NEXI-002) from allogeneic or autologous T cells. Applications relating to our NEXI-001 and NEXI-002 programs remain pending in all jurisdictions for which we have filed patent applications, including more recent patent applications that relate in part to the NEXI-001 and NEXI-002 composition of matter. In addition, we control issued or allowed patents in the United States, Australia, Brazil, China, Israel, India, Japan, South Korea, Mexico, and Europe (through the European Patent Convention) that relate to our AIM INJ programs, including patents covering compositions of matter and methods of use. Applications relating to our AIM INJ programs remain pending in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, Russian Federation, South Korea, Singapore, and United States. We have and will continue to actively protect our intellectual property, including filing patent applications for our innovations, prosecuting our pending patent applications, and maintaining and enforcing our issued patents. We currently have one pending PCT Application and one pending U.S. provisional application relating to both our cell therapy and AIM INJ technology. No assurances can be given that pending patent applications will result in the issuance of a patent or that the examination process will not require us to narrow our claims. In addition, issued patents may be circumvented by third parties, or found unenforceable or invalid if contested before a court or administrative agency. Thus, we may not be able to successfully enforce our patent rights against third parties. No assurance can be given that others will not independently develop a similar or competing technology or design around any patents that may be issued to us.

Each of our patents, if and when granted, will generally have a term of 20 years from its earliest, non-provisional filing date, subject to available extensions. Our patents and, if granted, patent applications have expiry dates ranging from 2034 to 2044.

For more comprehensive risks related to our proprietary technology and processes, please see the section of this filing on Form 10-K captioned "*Risk Factors—Risks Related to Intellectual Property.*"

Government Regulation and Product Approval

Therapeutic products are subject to rigorous regulation by the FDA and other governmental agency regulations in the United States and in foreign countries. Noncompliance with applicable requirements can result in import detentions, fines, civil penalties, injunctions, suspensions or losses of regulatory approvals or clearances, recall or seizure of products, operating restrictions, denial of export applications, governmental prohibitions on entering into supply contracts, and criminal prosecution. Failure to obtain regulatory approvals or the restriction, suspension or revocation of regulatory approvals or clearances, as well as any other failure to comply with regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations. In connection with therapeutic approval, we will have to comply with the many requirements associated with preclinical and clinical trials, the FDA application process, the terms of any pre-certification protocols and agreements, FDA manufacturing requirements for prototypes, and testing. Upon approval of a Biologics License Application, or BLA and similar approvals in other jurisdictions, there will be additional regulation relating to the packaging, distribution, marking, marketing and claims of our potential products. These later regulations are not only found in federal regulation but many states and, of course, foreign countries.

The U.S. FDA Process

The FDA regulates the clinical testing and design of therapeutics to ensure that medical products distributed in the United States are safe and effective for their intended uses. The application process for a new therapeutic is highly regulated.

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation by relevant authorities. Our potential products will be regulated as biologics. With this classification, commercial production of our potential products will need to occur in registered and licensed facilities in compliance with current good manufacturing practices, or cGMP, established by the FDA for biologics. The FDA categorizes human cells, tissues, or cellular or tissue-based products, or HCT/Ps, as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization.

Government authorities in the United States (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 candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in a foreign country. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, 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. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Services Act, or PHSA, and their respective implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The FDA has limited experience with commercial development of T cell therapies for cancer, including direct-injectable technologies such as AIM INJ. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practice, or GLP, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice, or GCP, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with 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, compliance with the FDA's current good tissue practice, or cGTP, for the use of human cellular and tissue products;

- potential FDA audit of the trial and clinical trial sites that generated the data in support of the BLA;
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable; and
- FDA review and approval, or licensure, of the BLA.

Preclinical studies

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 candidate's biological characteristics, chemistry, toxicity, stability 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 GLP. 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. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

Human clinical trials in support of a BLA

Clinical trials involve the administration of the biological product candidate to human research subjects 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. An 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 and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a clinical trial involving a biological product candidate at any time before or during the trial due to safety concerns or non-compliance. If the FDA imposes a clinical hold, the trial may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or that, once begun, issues will not arise that suspend or terminate such trials.

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 independent IRB at or servicing each institution at which the clinical trial will be conducted, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB is charged with protecting the welfare and rights of 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 form that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. In certain cases, 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.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Information related to the investigational product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical trial or to submit trial results as provided for in the law can give rise to civil monetary penalties and prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have recently begun enforcing those requirements against non-compliant clinical trial sponsors.

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

- *Phase I*. The product candidate is initially introduced into human subjects to test for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase II*. The biological product candidate is evaluated in a limited patient population to identify possible safety risks (adverse effects), optimize dosing and preliminarily evaluate the efficacy of the product candidate for specific targeted diseases.

- *Phase III*. Clinical trials are undertaken in an expanded patient population to further evaluate dosage, clinical efficacy, and safety, often at geographically dispersed trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval clinical trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events, or SAEs, occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, GCP, or other IRB requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor known as the data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints.

During the development of a new drug or biological product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase II, and before submission of a BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase II meeting to discuss their Phase II clinical results with the agency and to present their plans for the pivotal Phase III studies that they believe will support approval of the new drug or biological product.

Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of subjects the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

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 drug 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 drug candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. A BLA must contain

sufficient evidence of the biological product candidate's safety, purity, potency and efficacy for its proposed indication or indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

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

According to the goals and policies for original BLAs agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. For all original BLAs, the ten and six-month time periods run from the filing date; for all other submissions, including resubmissions, efficacy supplements and other supplements, the FDA's stated review time periods, ranging from two to ten month, run from the submission date. Despite these review goals, it is not uncommon for FDA review of a BLA to extend beyond the goal date.

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. Most such applications are meant to be reviewed within ten months from the date it is accepted for filing, and most applications for "priority review" products are meant to be reviewed within six months from the date the application is accepted for filing. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

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 final decisions on approval. The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. 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 typically conduct a pre-approval inspection of 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 cell- or tissue-based immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the cGTP, to the extent applicable. The FDA's cGTP regulations and guidance documents govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTP requirements is to ensure that cellular tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. 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 assure cGMP, cGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

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. A sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration is required to submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase III or Phase II/III clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials or other clinical development programs. 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).

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 or may require additional clinical or other data and information. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. On the basis of the FDA's evaluation of the BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete. and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase III clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may choose to either resubmit the BLA addressing all of the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase IV clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, Breakthrough Therapy Designation and priority review designation and regenerative medicine advanced therapy designation.

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast-track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the

submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, with the enactment of FDASIA in 2012, Congress created a new regulatory program for product candidates designated by FDA as "breakthrough therapies" upon a request made by the IND sponsors. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval of their respective marketing applications. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, which are intended to expedite the development and review of an application for approval of a breakthrough therapy.

Finally, the FDA may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

As part of the 21st Century Cures Act, congress created an accelerated approval pathway for regenerative medicine advanced therapies, or RMATs, which includes therapeutic tissue engineered products, human cell and tissue products, cell therapies and combination products using any such therapies. The program is intended to facilitate efficient development and expedite review of regenerative medicine therapies that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition.

A sponsor may request a RMAT designation from the FDA concurrently with or any time after the IND submission. The FDA has 60 calendar days to determine if the drug product meets the required criteria. Preliminary clinical evidence that the product has the potential to address a serious unmet need or condition is expected, is not required to indicate that the drug product may offer significant improvement over current therapies. The RMAT designation provides the same benefits of the fast track and breakthrough designation programs and programs may be eligible for priority review. Products with the RMAT designation may also be eligible for accelerated approval if pre-agreed criteria are met.

Accelerated Approval Pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM 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 receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of

clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug. All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Orphan Drug Designation and Exclusivity

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

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity. During the seven-year exclusivity period, the FDA may not approve any other applications to market a product containing the same active moiety for the same disease, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product as defined by the FDA and we are not able to show the clinical superiority of our product candidate or if our product candidate's indication is determined to be contained within the competitor's product orphan indication. In addition, the FDA will not recognize orphan drug exclusivity if a sponsor fails to demonstrate upon approval that the product is clinically superior to a previously approved product containing the same active moiety for the same orphan condition, regardless of whether or not the previously approved product was designated an orphan drug or had orphan drug exclusivity. A product that has received orphan drug designation may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received the designation. Orphan exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same product for a different disease or condition.

The period of orphan exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the disease or condition for which the product has been designated. In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the Agency to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." It is unclear how this court decision will be implemented by the FDA.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our biological products, some of our US patents may be eligible for limited patent term extension. These patent term extensions permit a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The USPTO in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Reference Product Exclusivity for Biological Products

In March 2010, the Patient Protection and Affordable Care Act, or ACA, was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, the FDA has approved a number of biosimilars, and numerous biosimilars have been approved in Europe. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, although to date no such products have been approved for marketing in the United States.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, the 12-year exclusivity period will be extended for an additional six months. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the

reference product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

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

Post-Approval Requirements

Any potential products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as off-label use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available medical products for off-label uses, if the physicians deem such uses to be appropriate in their professional medical judgment, it is FDA's position that manufacturers may not market or promote such off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the quality and long-term stability of the product. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP and cGTP requirements and satisfy the FDA or comparable foreign regulatory authorities before any product is approved and our commercial products can be manufactured. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP and cGTP regulations. These third-party manufacturers must comply with cGMP and cGTP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP and cGTP. Manufacturers, including third-party manufacturers, and other entities involved in the manufacture and distribution of approved biologics and HCT/Ps are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, cGTP, and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP and cGTP compliance, as applicable. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMP or cGTP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, voluntary recall and regulatory sanctions as described below.

Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse

effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Furthermore, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation Outside of the United States

In addition to regulations within the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 28-member European Union, before we may commence clinical trials or market products in those countries or areas. It is not yet clear how the United Kingdom's withdrawal from the European Union will affect the approval of medicinal products in the UK. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union drug development, review and approval

In the European Union, our product candidates also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

The new Clinical Trials Regulation (EU) No 536/2014, which became effective in January 2022, aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation. Investigational medicinal products used in clinical trials must be manufactured in accordance with good manufacturing practices. Other national and EU-wide regulatory requirements may also apply.

To obtain a marketing authorization of a drug in the European Union, we may submit marketing authorization applications, or MAA, either under the so-called centralized or national authorization procedures.

ATMP review and approval in the EU

In the EU, medicinal products, including advanced therapy medicinal products, or ATMPs, are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and Member State levels. Regulated in accordance with Regulation (EC) No 1394/2007, ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products. Gene therapy products deliver genes into the body that lead to a therapeutic, prophylactic or diagnostic effect. We anticipate that our NEXI-001 and NEXI-002 product candidates will be regulated as ATMPs in the EU.

To obtain regulatory approval of an ATMP under EU regulatory systems, we must submit a marketing authorization application, or MAA, under the centralized procedure administered by the European Medicines Agency, or EMA. The application used to submit a BLA in the United States is similar to the required application process in the EU, with the exception of, among other things, certain specific requirements set out in the ATMP Regulation, for example certain additional product characteristic information that must be included in the MAA. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid across all of the EU. As provided for in the ATMP Regulation, the scientific evaluation of MAAs for ATMPs is primarily performed by a specialized scientific committee called the Committee for Advanced Therapies, or CAT. The CAT prepares a draft opinion on the quality, safety and efficacy of the ATMP which is the subject of the MAA, which is sent for final approval to the Committee for Medicinal Products for Human Use, or CHMP. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EU Member States. The maximum timeframe for the evaluation of a MAA for an ATMP is 210 days from receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CAT and/or CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, which makes and issues the final decision to grant a marketing authorization within 67 days of receipt of the EMA's recommendation. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the United Kingdom

medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

Conditional approval

In specific circumstances, E.U. legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric studies

Prior to obtaining a marketing authorization in the EU, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

European Union regulatory exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

European Union orphan designation and exclusivity

The criteria for designating an orphan medicinal product in the European Union, are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC)

847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

PRIME designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure. Eligible products must target conditions for which where is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated Agency contact and rapporteur from the CHMP or CAT are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Periods of authorization and renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Brexit and the regulatory framework in the United Kingdom

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, in March 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the United Kingdom. This transition period ended on December 31, 2020. Since the regulatory framework in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory

regime which applies to products and the approval of product candidates in the United Kingdom as United Kingdom legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom in the long-term. The MHRA, the United Kingdom medicines and medical devices regulator, has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now that the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products evolves over time. On June 28, 2021, the European Commission issued a decision that the United Kingdom ensures an adequate level of protection for personal data transferred under the GDPR from the European Union to the United Kingdom.

Rest of the world regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage, Pricing and Reimbursement

Sales of pharmaceutical products approved by the FDA will depend in significant part on the availability of third-party coverage and reimbursement for the products. Third-party payors include government healthcare programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Further, there is no uniform policy for coverage and reimbursement in the United States. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or other comparable regulatory approvals.

Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

Furthermore, coverage and reimbursement for products can differ significantly from payor to payor. One payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. In the United States, the principal decisions about reimbursement for new medicines are typically made by the U.S. Centers for Medicare & Medicaid Services, or CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Moreover, 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. Payment methodologies may also be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. There also has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. By way of example, in August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so-called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other Member States allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be priced significantly lower.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution (arbitrage between low-priced and high-priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other U.S. Health Care Laws and Regulations

Although we currently do not have any products on the market, our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors expose us to broadly applicable healthcare regulation and enforcement by the U.S. federal government and the states and foreign governments in which we conduct our business, such as fraud and abuse, transparency and health information privacy rules and regulations. These laws include, without limitation:

- the federal anti-kickback statute, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;

- the federal false claims laws, including the False Claims Act provides for civil whistleblower or qui tam actions, and the civil monetary penalties law, which among other things prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to 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, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, for covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their business associates and covered subcontractors that provide services to, or on behalf of, the covered entity that involve individually identifiable health information;

- the federal transparency requirements under the Physician Payments Sunshine Act require certain manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services, or DHS, information related to payments and other transfers of value to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives;

- the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials, which prohibit U.S. companies and their employees, officers, and representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official (including, potentially, healthcare professionals in countries in which we operate or may sell our products), government staff member, political party, or political candidate to obtain or retain business or to otherwise seek favorable treatment; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by nongovernmental third-party payors, including private insurers.

In November 2020, the DHHS finalized significant changes to the regulations implementing the AKS, as well as the Physician Self-Referral Law (Stark Law) and the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. In addition, state and local laws may require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violations of any of such laws or any other governmental regulations that apply to us, may subject us to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business.

Health Care Reform in the United States and Potential Changes to Health Care Laws

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. 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 otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

As previously mentioned, a primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding. As previously mentioned, a primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

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

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical and biologic products. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. In addition to the sweeping reforms contained in the ACA, other legislative changes have been proposed and adopted in the United States that may affect health care expenditures. For example, the 2020 Consolidated Appropriations Act (P.L. 116-94) included a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS program for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

The Biden Administration, which assumed control of the Executive Branch on January 20, 2021, has indicated that lowering prescription drug prices is a priority. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on a Trump administration notice-and-comment rulemaking on Canadian drug importation that was finalized in October 2020). The Biden order also called on HHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing HHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions.

We expect that federal, state and local governments in the United States will continue to consider legislation directed at lowering the total cost of health care. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers, or PBMs, and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved, if approved. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Employees and Human Capital Resources

As of March 1, 2024, we had six full-time employees. Of these employees, three were engaged in research and development activities. Substantially all of our employees are based in Gaithersburg, Maryland. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources 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 our objectives. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Corporate Information

We were incorporated in Delaware in 2011. Our principal executive offices are located at 9119 Gaither Road, Gaithersburg, MD 20877, and our telephone number is (301) 825-9810. Our website address is *www.neximmune.com* and the information contained in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K and should not be considered part of this Annual Report on Form 10-K.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission, or the SEC, under the Securities Exchange Act of 1934, or the Exchange Act. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

We also make available free of charge on our Internet website at *www.neximmune.com* our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These reports are available through the "Investor Relations—Financials and Filings—SEC Filings" section of our website.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee and Nominating and Governance Committee are available through our Internet website at *www.neximmune.com*.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this Annual Report Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware

of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Following is a summary of our Risk Factors:

- We require substantial additional funding. If we are unable to raise capital, we may be unable to complete the development and commercialization of our product candidates and we could be required to complete a wind down of our operations and/or seek bankruptcy protection.
- We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.
- Our shares of common stock could be delisted from the Nasdaq Capital Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.
- We have incurred significant operating losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- If we are unable to successfully obtain approval for and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.
- Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed.
- We plan to initially target a small number of patients with our product candidates, and the market opportunities for these product candidates, if and when approved, may be limited to those patients who are ineligible for established therapies or have failed prior treatments and, accordingly, the opportunities may be small.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The AIM technology is a novel immunotherapy platform and therapies derived from it have not been tested in humans before. As a result, only limited human study data is available and it remains not fully known as to what kind of cytokines may be released.
- If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, if approved, and our ability to generate revenue will be materially impaired.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Our product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- Our product candidates are biologics and the manufacturing process for our product candidates is complex, generally more costly than traditional small molecule chemical compounds, and more difficult to reproduce. If we or any of our third-party manufacturers encounter manufacturing difficulties, our ability to provide or secure supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- We rely on, and expect to continue to rely on, third parties to conduct our clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates, and our business could be substantially harmed.

- The third parties upon which we rely for the supply of the source materials, are our sole sources of supply and have limited capacity, and the loss of any of these suppliers could harm our business.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to obtain and maintain intellectual property protection for our technology and products, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

A detailed discussion of the above Risk Factors follows below.

Risks Related to Our Business and Industry

We are a clinical-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical-stage biopharmaceutical company that was formed in June 2011. We have no products approved for commercial sale and have not generated any revenue. We are focused on developing immunotherapy products in which the body's immune system orchestrates a targeted T cell response against disease-relevant cells. Although there have been significant advances in cell-based immunotherapy, our T cell technologies are new and largely unproven. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies, and conducting clinical trials. If one of our product candidates received regulatory approval, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. In addition, our limited operating history, particularly in light of the rapidly evolving cancer immunotherapy field, may make it difficult to evaluate our current business and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses in for the foreseeable future and may never achieve or maintain profitability.

We are not profitable and have incurred significant losses in each period since our inception, including net losses of $32.3 million and $62.5 million for the years ended December 31, 2023 and 2022, respectively. We have not commercialized any products and have never generated any revenue from product sales. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our product candidates, scale-up manufacturing capabilities and hire additional personnel to support the development of our product candidates and to enhance our operational, financial and information management systems.

A critical aspect of our strategy is to invest significantly in our technology platform to improve the efficacy and safety of our product candidates. To become and remain profitable, we must develop and eventually commercialize products with significant market potential, which we may never achieve. Even if we succeed in commercializing one or more of these product candidates, we will continue to incur losses for the foreseeable future relating to our substantial research and development expenditures to develop our technologies. 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. Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our discovery and preclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in the value of our company could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in June 2011, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking nonclinical studies and conducting clinical trials. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes several years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We have never generated any revenue from product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or the FDA, or other regulatory agencies, domestic or foreign, or other comparable foreign authorities, to perform preclinical studies or clinical trials in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether w**.** own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

If we fail to obtain additional financing on acceptable terms or at all, we may be unable to complete the development and commercialization of our product candidates and we could be required to complete a wind down of our operations and/or seek bankruptcy protection.

Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates. We would have to spend substantial amounts to conduct research and development and preclinical or nonclinical testing and studies and clinical trials, to build a supply chain, to seek regulatory approvals for any product candidates we may develop. If we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company in the United States.

As of December 31, 2023, we had $3.2 million in cash, cash equivalents, and available-for-sale marketable securities. In February 2021, we completed the IPO for net proceeds of $114.6 million after deducting underwriting discounts and commissions and offering expenses. We believe that, based upon our current operating plan, our existing capital resources will not be sufficient to meet our anticipated cash requirements for at least twelve months from the issuance of these financial statements. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. In addition, our future capital requirements will depend on many factors, and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of nonclinical development, laboratory testing and clinical trials for our product candidates;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel; and
- the costs associated with being a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Our ability to raise additional funding will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. We expect that additional funding will be highly dilutive to holders of our common stock. Such additional funding could involve the issuance and sale of redeemable or convertible preferred stock which terms may include liquidation preferences, price resets or other anti-dilution protections, or other equity or debt securities senior to our common stock, that would provide their holders with significant preferences and other rights over our common stock and which could reduce or eliminate some or all of the value of the common stock and any other securities exercisable for or convertible into our common stock. The additional funding may result in certain governance and other board rights being provided to investors in such a financing. In addition, our ability to obtain future funding when needed through equity financings, debt financings or strategic collaborations may be particularly challenging in light of the continued uncertainties and circumstances regarding the current market conditions, any pandemics, regional conflicts, sanctions, labor conditions or geopolitical events. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we could be required to complete the wind down of our operations and/or seek bankruptcy or similar protection. As a result, our business, financial condition and results of operations would be materially affected and our stockholders would lose all of their investment. Our license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

We currently have a shelf registration statement effective, however, our ability to raise capital under this registration statement may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Based on our public float, as of the date of the filing of this Annual Report on Form 10-K, we are only permitted to utilize a shelf registration statement subject to Instruction I.B.6 to Form S-3, which is referred to as the "baby shelf" rule. For so long as our public float is less than $75.0 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Pursuant to our announced strategic realignment announced in November 2022, we have paused clinical trials for our AIM ACT cell therapy product candidates in order to realign our focus on our AIM INJ preclinical programs. If we fail to execute successfully on this realigned strategic focus, our business and prospects may be adversely affected.

In November 2022, we announced that we are pausing our clinical trials for NEXI-001 and NEXI-003, and that our clinical trial for NEXI-002 will remain paused, in order to realign our focus on development of the AIM INJ platform. We believe this realigned strategic focus is the best way to optimize our financial and other resources to advance our business. However, there is no assurance that we will be successful at executing on this strategy, and we cannot currently specify when, if ever, we will be able to resume clinical development of NEXI-001, NEXI-002 or NEXI-003. If we are unable to execute successfully on this realigned strategic focus, our business and prospects may be adversely affected.

Our future success depends on our ability to retain our chief executive officer and certain other key executives and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the experience of Kristi Jones, our President and Chief Executive Officer, as well as certain other principal members of our management, scientific and R&D teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time.

In October 2023, our board of directors implemented a reduction-in-force of substantially all of our employees, other than key members of our management, scientific and R&D teams necessary to implement the wind up and support the efforts to maximize the value of our business and our assets. The uncertainty inherent in this reduction-in-force caused concerns from third parties with whom we do business, and increased the likelihood of turnover of other key officers and employees.

If we lose key members of management, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing such members may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully.

Our strategic refocus and the associated reduction-in-force could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

There can be no assurance that our strategic refocus and the associated reduction-in-force will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Our workforce reductions may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, our workforce reductions can require a significant amount of time and focus from management and other employees, which may divert attention from operations. Further, our workforce reductions may result in unexpected expenses or liabilities and/or write-offs. If our workforce reductions fail to achieve some or all of the anticipated benefits, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, which may force us to complete a wind down of our operations and/or seek bankruptcy protections.

We had cash, cash equivalents, and marketable securities of $3.2 million as of December 31, 2023, which we believe that should be sufficient to fund our operating plan into the second quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Pursuant to the requirements of ASC 205-40, Presentation of Financial Statements - Going Concern, and as a result of our financial condition and other factors

described herein, there is substantial doubt about our ability to continue as a going concern for a period of at least twelve months from the date of the financial statements. Our ability to continue as a going concern will depend on our ability to obtain substantial additional funding. Adequate additional financing may not be available to us on acceptable terms, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional securities, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities will substantially dilute all of our stockholders. We could also be required to seek funds through arrangements with potential collaboration partners, including at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, our board of directors will need to consider the interests of all our constituents and take appropriate action, including to restructure or wind down the business, if it appears that we are insolvent. If we are unable to obtain additional funding on a timely basis, we may resume pursuit of a wind down of our operations and/or seek bankruptcy or similar protection. As a result, our business, financial condition and results of operations would be materially affected and our stockholders would lose all of our investment.

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach may be different. The competition comes from both biotechnology firms and from major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than us. We also experience competition in the development of our immunotherapies from universities, other research institutions and others in acquiring technology from such universities and institutions.

In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

The successful development of immunotherapies is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and depends on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or preparation of Biologics License Application, or BLA, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payors were not to provide adequate coverage and reimbursement levels for any of our products once approved, market acceptance and commercial success would be reduced.

Our technology platform, including our proprietary Artificial Immune Modulation, or AIM, technology is a new approach to treat cancer and other immune-related diseases that presents significant challenges.

We have concentrated our research and development efforts on advancing a new generation of immunotherapies based on the AIM technology, and our future success is highly dependent on the successful development of our product candidates, which target cancer and other immune-related diseases. Our technology platform is the foundation for our innovative approach to immunotherapy in which the body's immune system orchestrates a targeted T cell response against disease-relevant cells. Central to the AIM technology are synthetic dendritic cells that present antigens to T cells eliciting a targeted therapy driven by the patient's immune system. Because this is a new approach to immunotherapy and for the treatment of cancer and other immune-related diseases generally, developing and commercializing our product candidates subjects us to a number of challenges, including:

- educating medical personnel about the administration of the AIM product candidates;
- educating medical personnel regarding the potential side effect profile of our product candidates, such as the potential adverse side effects related to cytokine release syndrome, neurotoxicity or autoimmune or rheumatologic disorders. As the AIM technology is a novel immunotherapy platform and therapies derived from it have not been tested in humans before, only limited human study data is available, and it remains not fully known as to what kind of cytokines may be released. Medical personnel will need to continue to monitor on an ongoing basis;
- administering chemotherapy to patients in advance of administering our product candidates, which may increase the risk of adverse side effects;
- sourcing clinical and, if approved, commercial, supplies for the materials used to manufacture and process our product candidates;
- manufacturing the proteins necessary for the cell therapy and injections and issues with our facility, quality control or general production process may arise, which could delay the development of our product candidates;
- developing AIM INJ, a direct-injectable modality of the AIM technology that has not previously been demonstrated and may not work as originally contemplated;
- potentially moving the development of AIM INJ into the clinic, and addressing uncertainty around the regulatory requirements that may need to be met in connection with such an investigational new drug application, or IND;
- managing the risk in relying on one single source for the production of AIM nanoparticles, including the risk that if that source is unable to provide us with the necessary particles that may result in significant delays to our clinical trials;
- developing a robust and reliable T cell manufacturing process, including efficiently managing shipment of patient cells from and to clinical sites, minimizing potential contamination to the cell product and effectively scaling manufacturing capacity to meet demand;
- managing costs of inputs and other supplies while scaling production;
- using medicines to manage adverse side effects of our product candidates, which may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;
- obtaining and maintaining regulatory approval from the FDA;

- addressing the broader uncertainty around the regulatory requirements and pathway for the approval of an adoptive cell therapy;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

We cannot be sure that our AIM technology will yield satisfactory products that are safe and effective, scalable, or profitable.

Although we are a cell therapy company our technology could become subject to many of the challenges and risks that gene therapies face, including:

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future.
- the FDA could recommend follow-up observation period of up to 15 years for all patients who receive our treatment. We may need to adopt such an observation period for our product candidates.
- clinical trials using genetically modified cells conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health, or the NIH, are subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC. Although the FDA decides whether individual protocols may proceed, the RAC review process can impede the initiation of a clinical trial, even if the FDA has reviewed the study and approved its initiation.

Moreover, public perception of therapy safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Our near-term ability to generate product revenue is dependent on the success of one or more of our product candidates, each of which are at an early-stage of development and will require significant additional clinical testing before we can seek regulatory approval and begin commercial sales.

Our near-term ability to generate product revenue is highly dependent on our ability to obtain regulatory approval of and successfully commercialize one or more of our product candidates. All of our product candidates are in the early stages of development and will require additional clinical and nonclinical development, regulatory review and approval in each jurisdiction in which we intend to market the products, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety, purity, and potency of the product candidates in humans. We cannot be certain that any of our product candidates will be successful in clinical trials and they may not receive regulatory approval even if they are successful in clinical trials.

Before we can generate any revenues from sales of our lead product candidates, we must complete the following activities for each of them, any one of which we may not be able to successfully complete:

- conduct additional preclinical and clinical development with successful outcomes;
- manage preclinical, manufacturing and clinical activities;
- obtain regulatory approval from the FDA and other comparable foreign regulatory authorities;
- establish manufacturing relationships for the clinical and post-approval supply of the applicable drug candidate in compliance with all regulatory requirements;
- build a commercial sales and marketing team, either internally or by contract with third parties;
- establish and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- develop and implement marketing strategies for successful commercial launch of our product candidates, if and when approved;

- secure and maintain acceptance of our products, if and when approved, by patients, from the relevant medical communities and from third-party payors;
- compete effectively with other therapies;
- establish and maintain adequate health care coverage and reimbursement from third-party payors;
- ensure continued compliance with any post-marketing requirements imposed by regulatory authorities, including any required post-marketing clinical trials or the elements of any post-marketing Risk Evaluation and Mitigation Strategy, or REMS, that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of the product outweigh its risks;
- maintain continued acceptable safety profile of the product candidates following approval; and
- invest significant additional cash in each of the above activities.

If we are unable to address one or more of these factors in a timely manner or at all, we could experience significant delays in the successful commercialization of, or an inability to successfully commercialize, our product candidates, which would materially harm our business. If we do not receive regulatory approvals for one or more of our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to manufacture and market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

In addition, because NEXI-001 and NEXI-002 are clinical-stage candidates, and because our other product candidates are based on similar technology, if NEXI-001 and NEXI-002 were to encounter safety or efficacy problems, developmental delays, regulatory issues, or other problems, our development plans and business could be significantly harmed. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business.

We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on trial design;
- the FDA may not allow us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical trials;
- our INDs have been approved in a timely manner thus far, however the FDA may not agree with our approach and strategy, which could result in potential delays, and changes to our regulatory strategy;
- we may be required to complete additional preclinical studies in HLAs before we can proceed with our INDs;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or trial sites; developments on clinical trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical trials;
- difficulty collaborating with patient groups and investigators;

- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's current good clinical practice regulations, or cGCPs, requirements, or similar applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- patients dropping out of a trial;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- delays in developing our manufacturing processes and transferring to new third-party facilities to support future development activities and commercialization that are operated by contract manufacturing organizations, or CMOs, in a manner compliant with all regulatory requirements; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

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

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional trials to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our product candidates may be delayed, and our business will be harmed.

From time to time, we provide timing estimates regarding the initiation of clinical trials and clinical development milestones, and the expected availability of data resulting from these trials for certain of our product candidates. We expect to continue to estimate the timing of these types of development milestones and our expected timing for the accomplishment of various other scientific, clinical, regulatory and other product development objectives. However, the achievement of many of these milestones and events may be outside of our control. All of these timing estimations are based on a variety of assumptions we make which may cause the actual timing of these events to differ from the timing we expect, including:

- our available capital resources and our ability to obtain additional funding as needed;
- the rate of progress, costs and results of our clinical trials and research and development activities;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, European Medicines Agency, or EMA, and other regulatory authorities and the timing of these approvals;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- the efforts with respect to the commercialization of our product candidates;
- the securing of, costs related to, and timing issues associated with, manufacturing our therapeutic;
- candidates and, if any of our product candidates are approved, associated with sales and marketing activities and the commercial manufacture of our product candidates; and

- circumstances arising from or relating to the COVID-19 pandemic, including potential effects on the global supply chain, our manufacturers and the availability of raw materials needed for the research and development of our product candidates.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business and results of operations may be harmed and our stock price may decline.

Failure to successfully identify, develop and commercialize additional therapeutics or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, we expect to continue to innovate and potentially expand our portfolio. Because we have limited financial and managerial resources, research programs to identify product candidates may require substantial additional technical, financial and human resources, whether or not any new potential product candidates are ultimately identified. Our success may depend in part upon our ability to identify, select and develop promising product candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional product candidates suitable for further development. All product candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics indicating that it is unlikely to receive approval by the FDA, the EMA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize new product candidates we have identified and explored, our business, prospects, financial condition and results of operations could be adversely affected.

We face risks related to health, pandemics, epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. As a recent example, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States, Europe, and certain other countries. In the years following the initial outbreak, numerous state and local jurisdictions imposed quarantines, shelter-in-place orders, executive orders, and similar government orders for their residents to control the spread of COVID-19.

A significant outbreak of other infectious diseases in the future also could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans, and we may fail to obtain regulatory approval of our product candidates.

The FDA standard for approval of a biologic generally requires two well-controlled Phase III studies or one large and robust, well-controlled Phase III study in the patient population being studied that provides substantial evidence that a biologic is safe and effective for its proposed indication. Phase III clinical trials typically involve hundreds of patients, have significant costs and take years to complete. Product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA usually requires a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. Although we intend to request accelerated approval status for NEXI-001 and NEXI-002, we can provide no assurance that the FDA will grant such designation for either product candidate, nor can we provide any assurance that even if the FDA grants such designation that it will improve the likelihood that the agency will ultimately approve either product candidate.

As part of its marketing authorization process, the EMA may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use, or CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for

human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete nonclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats.

Conditional marketing authorizations are valid for one year, on a renewable basis. The holder is required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

The granting of a conditional marketing authorization allows medicines to reach patients with unmet medical needs earlier than might otherwise be the case and ensure that additional data on a product are generated, submitted, assessed and acted upon. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied.

Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;
- 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 the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be 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 the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third-party manufacturer's facilities 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.

Further, failure to obtain approval for any of the above reasons may be made more likely due to the novel nature of our AIM technology. Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects.

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

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. We expect there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our product candidates which involve personalized T cell therapy, than for "off-the-shelf" products, like small molecule drugs which are not personalized for each patient. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

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

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

As with most biological products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials.

The FDA or comparable foreign regulatory authorities could delay or deny approval of our product candidates for any or all targeted indications and negative side effects could result in a more restrictive label for any product that is approved. Side effects such as toxicity or other safety issues associated with the use of our product candidates could also require us or our collaborators to perform additional studies or halt development or sale of these product candidates.

Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, as toxicities resulting from personalized T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand their potential side effect profiles, both for our planned clinical trials and upon any commercialization of any product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in adverse effects to patients, including death. Any of these occurrences may materially harm our business, financial condition and prospects.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approvals of such products;

- regulatory authorities may require the addition of labeling statements, specific warnings or a contraindications;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we may be required to change the way such products are distributed or administered, or change the labeling of the products;
- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the products;
- we may decide to recall such products from the marketplace after they are approved;
- we could be sued and held liable for harm caused to individuals exposed to or taking our products; and
- our reputation may suffer.

In addition, adverse side effects caused by any therapeutics that may be similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

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

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

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving T cell based immunotherapy;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials will compete with other 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 trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. 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 hematopoietic cell transplantation, rather than enroll patients in any future clinical trial.

Even if we are able to enroll a sufficient number of patients in our clinical trials, 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 trials and adversely affect our ability to advance the development of our product candidates.

Clinical trials are expensive, time-consuming and difficult to design and implement, and our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.

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 new technologies and manufactured on a patient-by-patient basis, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products.

In addition, one of our early-stage product candidates that is currently in preclinical development is for a novel class of injectable biologics. Development of the underlying technology may be affected by unanticipated technical, regulatory, manufacturing or other problems, among other research and development issues, and the possible insufficiency of funds needed in order to complete development of this product candidate.

Our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. Depending on the number of patients we ultimately enroll in our trials, and the number of trials we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments.

Research and development of biopharmaceutical products is inherently risky. We may not be successful in our efforts to use and enhance our AIM technology platform to create a pipeline of product candidates and develop commercially successful products, or we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited.

We are pursuing clinical development of product candidates developed employing our AIM technology. We are at an early stage of development and our technology platform has not yet led, and may never lead, to approved or commercially successful products.

Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of this transaction and are prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Even if we receive FDA approval to market additional product candidates, whether for the treatment of cancers or other diseases, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the

marketplace or more effective than other commercially available alternatives. Further, because of our limited financial and managerial resources, we are required to focus our research programs on certain product candidates and on specific diseases. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. For additional information regarding the factors that will affect our ability to achieve revenue from product sales, see the risk factor above "*—We have never generated any revenue from product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors.*"

Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our product candidates are biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including harvesting T cells from patients, enriching and expanding T cells *ex vivo*, and ultimately infusing the T cells back into a patient's body. As a result of the complexities, the cost to manufacture biologics in general, and our modified cell product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with harvesting T cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's starting material or later-developed product at any point in the process, the manufacturing process for that patient may need to be restarted and the resulting delay may adversely affect that patient's outcome. Our product candidate relies on donor's providing their blood, which is used to harvest T-cells. If issues arise with the product candidate, the donor may need to wait three months before they are able to donate again. This could result in the patient not being treated. Additionally, if microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. As a result of the complexities of our manufacturing process, we have in the past encountered difficulties in producing our product candidates. For example, our manufacturer has in prior instances produced batches of the active ingredient in our product candidate that did not meet the dosing requirement of our clinical trial protocol.

Our manufacturing strategy involves the use of one or more CMOs, and we expect in the future to establish our own capabilities and infrastructure, including a manufacturing facility. We expect that development of our own manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience as a company in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to

specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

We rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or price, or fail to maintain or achieve satisfactory regulatory compliance.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and currently rely on a single source vendor to manufacture supplies and process our product candidates, which is and will need to be done on a patient-by-patient basis. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

Although in the future we do intend to develop our own manufacturing facility, we also intend to use third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. Our anticipated reliance on a limited number of third-party manufacturers 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 the FDA must approve any manufacturers. This approval would require new testing and GMP and current good tissue practices, or cGTP compliance inspections by FDA, as applicable. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products.
- Our manufacturers may have little or no experience with autologous cell products, which are products made from a patient's own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates.
- Our third-party manufacturers might be unable to timely manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately.
- Our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our products, 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 the FDA and corresponding state agencies to ensure strict compliance with current cGMP, or cGTP, if applicable and other government regulations and corresponding foreign 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.
- Raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects.
- Our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.
- Our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we

will rely on third parties to perform certain specification 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 and the FDA could place significant restrictions on our company until deficiencies are remedied.

In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. Although our agreements with our CMOs require them to perform according to certain cGMP and, if applicable, cGTP requirements such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If any of our CMOs cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA, EMA or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our drug candidates unless and until we engage a substitute CMO that can comply with such requirements, which we may not be able to do. In addition, our CMOs are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter are subject to ongoing inspection from time to time. Our CMOs may not be able to comply with applicable cGMP or cGTP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Any such failure by us or any of our CMOs would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

Our third-party manufacturers may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing any approved product candidates.

Our manufacturing partners may be unable to successfully increase the manufacturing capacity for our product candidates in a timely or cost-effective manner, or at all, as needed for our development efforts or, if our product candidates are approved, our commercialization efforts. Quality issues may also arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting therapeutic may be delayed or not obtained, which could significantly harm our business.

Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all.

Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

We rely and will 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 or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will depend upon independent investigators and collaborators to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners, and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We rely and will rely heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to how they are providing and administering T cell therapy. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators, and 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 may require us to perform additional nonclinical or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the applicable GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP, and likely cGTP regulations 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 not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not 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.

Any agreements governing our relationships with CROs or other contractors with whom we currently engage or may engage in the future may provide those outside contractors with certain rights to terminate a clinical trial under specified circumstances. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

The market opportunities for our product candidates, if and when approved, may be limited to those patients who are ineligible for established therapies or have failed prior treatments and may be small.

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

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive third line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we expect to initially target a small patient population with our product candidates. NEXI-001 is being developed for the treatment of AML or MDS patients with relapsed disease after an allogeneic hematopoietic cellular transplant and NEXI-002 is being developed for the treatment of MM patients that have failed at least three prior lines of therapy. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy.

Our market opportunities may also be limited by competitor treatments that may enter the market. See the risk factor below "*—We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.*"

We plan to seek orphan drug status for some or all of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient 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 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 or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our drug candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We plan to seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products, including AML or MDS and MM, but exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective 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. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations.

We plan to seek but may fail to obtain breakthrough therapy designation for some or all of our product candidates.

As part of the enactment of Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, the Congress established a "breakthrough therapy" designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases when "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase I; organizational commitment involving senior managers; and eligibility for rolling review and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA, and such designation does not change the standards for product approval. We intend to seek breakthrough therapy designation for some or all of our product candidates for the treatment of AML or MDS and MM, but there can be no assurance that we will receive breakthrough therapy designation. Even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even after a product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell those product candidates in those countries or regions and our business could be substantially harmed.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug and biological products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries, where regulatory requirements for such products differ. We are not permitted to market any of our biological product candidates in the United States until we receive approval of a BLA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory authorities in such countries. The time required to obtain approval, if any, by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials, if approval is obtained at all, and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials. We have not submitted a marketing application such as a BLA to the FDA, an MAA to the EMA, or any similar application to any other jurisdiction. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we have and expect to continue to rely on third-party CROs to assist us in this process. Obtaining marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our CMOs that could result in the candidate not being approved. Moreover, we have not obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

Our biological product candidates could fail to receive, or could be delayed in receiving, regulatory approval for many reasons, including any one or more of the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA 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 support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate;
- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA, EMA or comparable foreign regulatory authorities;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and
- the change of the medical standard of care or the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, any drug candidates we are developing or may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and/or we may determine that further clinical development of any such product candidate is not justified and may discontinue any such programs.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our drug candidates.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing, or commercial product distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources, and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all products we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

A variety of risks associated with operating our business internationally could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements and reimbursement regimes 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 United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws;
- 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 United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism; and
- deteriorating relations between the United States and Russia resulting from the current situation involving Russia and Ukraine, including tariffs, economic sanctions and import-export restrictions imposed by either nation, and retaliatory actions by other nations.

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

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, and the rapidly evolving market for developing T cell therapies in particular, 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, 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 as well as 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.

Specifically, we face competition from companies developing T cell therapies such as Cue Biopharma, Atara Biotherapeutics, Iovance Biotherapeutics and Parvus Therapeutics. Even if we obtain regulatory approval of our product candidates, we may not be the first to market and that may affect the price or demand for our product candidates. Additionally, 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. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our product candidates, that

may prevent us from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances.

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, particularly our chief executive officer, Kristi Jones, who is an at-will employee, and our scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business.

We conduct our operations at our facility in Gaithersburg, Maryland, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of our region, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock option grants that vest over time. The value to employees of these equity grants 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. 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 all of these individuals or the lives of any of our other employees.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of March 1, 2024, we had 6 employees, all of whom are full-time. As our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

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

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

We may form or seek collaborations or 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, or 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.

Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our 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, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or 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.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- our inability to achieve desired efficiencies, synergies or other anticipated benefits from such acquisitions or strategic partnerships;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. If we are unable to raise additional capital through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us or third parties, such as CROs and CMOs. We and such third parties are subject to federal, state, and local laws and regulations in the United States governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our and such third parties' 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 third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. 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. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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.

We also engage third-party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, ransomware, malicious software, phishing schemes, and fraud. From time to time, we get notifications that such vendors experienced cyber security breaches. Our ability to monitor our vendors and service providers' data security is limited, and, in any event, third parties may be able to circumvent those security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our

or third-party service providers' systems. We and our third-party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure or other loss of, information. Any hacking or other attack on our or our third-party service providers' or vendors' systems, and any unauthorized access to, or disclosure or other loss of, information suffered by us or our third-party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, which could divert our management's attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing-attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches, which could cause us to incur significant expenses. Although we take reasonable steps to help protect confidential and other sensitive information from unauthorized access or disclosure, we also could be the target of phishing attacks seeking confidential information regarding our employees. Furthermore, while we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information may be transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us.

To the extent we or these third parties are found to have violated such laws, rules or regulations or that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

Our operations, and those of our third-party research institution collaborators, CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, 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. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. 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. All of our operations including our corporate headquarters are located in a single facility in Gaithersburg, Maryland. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We may become involved in securities litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities litigation has often followed certain significant business events, such as the announcement of a strategic restructuring or realignment. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential partnership or other opportunities, or the ultimate value our stockholders receive in any such partnership or other opportunity.

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. For example, 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. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities

or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing any approved products, these claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities (or the manufacturing processes and facilities of our third-party manufacturer) or our marketing programs, a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to 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 products we develop, alone or with collaborators. Although we currently carry $10,000,000 of clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also 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.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

For example, legislation enacted in 2017 informally titled, the Tax Cuts and Jobs Act, or the TCJA, made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses from taxable years beginning after December 31, 2017 to 80% of current year taxable income and the elimination of net operating loss carrybacks generated in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely) and the modification or repeal of many business deductions and credits. In addition, on March 27, 2020, former President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 public health emergency, including providing temporary relief from certain aspects of the TCJA that had imposed limitations on the utilization of certain losses, interest expense deductions, and minimum tax credits and provided temporary deferral of certain payroll taxes.

It cannot be predicted whether, when, in what form or with what effective dates new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

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

Our ability to use our U.S. federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

Unused losses for the tax year beginning before January 1, 2018, and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused losses generated in tax years beginning after December 31, 2017, under the TCJA will not expire and may be carried forward indefinitely, and generally may not be carried back to prior taxable years, except that, under the CARES Act, net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such U.S. federal net operating losses generated in tax years beginning after December 31, 2017, is limited to 80% of our taxable income. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future, some of which are outside our control. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to Government Regulation

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

The research, testing, manufacturing, labeling, approval, selling, import, export, adverse event reporting, record keeping, advertising, promotion, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive a Biologics License from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure, potent, and effective for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of T cell therapies for cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory approval to begin a trial, if applicable;
- the availability of financial resources to begin and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent institutional review board, or IRB;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol, not complying with GCP, or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMP for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. See the risk factor above *"—If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected"* for additional information on risks related to patient enrollment. Further, a clinical

trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Safety Monitoring Committee for such trial, or 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 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. 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.

Our third-party research institution collaborators may also experience similar difficulties in completing ongoing clinical trials and conducting future clinical trials of product candidates. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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 to 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 if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases cGTP, regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and cGTP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, 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, we will have to comply with requirements including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, cGTP, and GCP 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 the following among other things:

- restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- withdrawal of the product from the market;
- product recalls;
- warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or
- supplements to approved applications;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any of our ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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

In addition, if we were able to obtain accelerated approval of any of our product candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

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

The use of modified T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. For example, certain of the product candidates that we will be developing target a cell surface marker that may be present on cancer cells as well as non-cancerous cells. It is possible that our product candidates may kill these non-cancerous cells, which may result in unacceptable side effects, including death. Additional 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;
- any restrictions on concomitant us of other medications;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the size of the market for such drug candidate, based on the size of the patient subsets that we are targeting, in their territories for which we gain regulatory approval and have commercial rights;
- the safety of the drug candidate as demonstrated through broad commercial rights;
- the adequacy of supply 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 amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of adequate coverage, reimbursement, and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- support from patient advocacy groups
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; 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 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.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any product candidate of ours that receives marketing approval in the future.

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.

We are and will be subject to stringent privacy laws, cybersecurity laws, regulations, policies and contractual obligations related to privacy and security, and changes in such laws, regulations, policies or how they are interpreted or changes in related contractual obligations could adversely affect our business.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, processing, storage and use of personally-identifying information including comprehensive regulatory systems in the United States and European Union, which, among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations by us or third parties to whom we contract certain types of work (like clinical trials) could result in enforcement action against us or such third parties, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the US federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable

health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Some U.S. state governments have enacted or are considering enacting more stringent laws and regulations protecting personal information and data. For instance, California passed the California Data Privacy Protection Act of 2018 (the "CCPA"), which went into effect in January 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. In addition, the California Consumer Rights Act ("CPRA") was recently enacted to strengthen elements of the CCPA and becomes effective January 1, 2023. A number of other states have considered similar privacy proposals, with states like Virginia and Colorado enacting their own privacy laws (also scheduled to come into effect in January 1, 2023 and July 1, 2023, respectively). These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data.

In the EU, we may be subject to the General Data Protection Regulation (GDPR) which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR applies to any company established in the European Economic Area, or EEA, (which includes the EU Member States plus Iceland, Liechtenstein, and Norway) and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, special provisions affording greater protection to and requiring additional compliance measures for "special categories of personal data" including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), "privacy by design" requirements, and direct obligations on service providers acting as processors. The GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR may also impose additional compliance obligations relating to the transfer of data between us and our subsidiaries or other business partners. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU), issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II.* This decision (a) calls into question commonly relied upon data transfer mechanisms as between the EU Member States and the United States (such as the Standard Contractual Clauses) and (b) invalidates the EU-U.S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the EU to the United States. The CJEU is the highest court in Europe and the *Schrems II* decision heightens the burden on data importers to assess U.S. national security laws on their business and future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

While we continue to address the implications of the recent changes to EU data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EU and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

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.

Successful sales of our product candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to treat cancer and other immune-related diseases, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our products. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products

profitably. In particular, in 2010, the Patient Protection and the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. The ACA continues to significantly impact the United States' pharmaceutical industry. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the Act. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. The CARES Act and other COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through June 30, 2022 (a 1% sequester will apply from April 1, 2022 through June 30, 2022). In January 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. In addition, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs and review the relationship between pricing and manufacturer patient programs.

Moreover, 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. Payment methodologies may also be subject to changes in healthcare legislation and regulatory initiatives. For example, Centers for Medicare and Medicaid Services may develop new payment and delivery models, such as bundled payment models. There also has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. By way of example, in August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, particularly as a result of the new presidential administration. The continuing

efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

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 fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with applicable laws and regulations 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 United States 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 United States, 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 subjects, 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, which could result in significant regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or 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 significant fines or other sanctions.

Our relationships with prescribers, purchasers, third-party payors and patients will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of our drug candidates, if approved, we will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other health care providers and third-party payors will play a primary role in the recommendation, prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain marketing approval. Restrictions under applicable domestic and foreign health care laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal health care program such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- U.S. federal false claims, false statements and civil monetary penalties laws, including the U.S. False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to

be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers;
- the FCPA and other anti-corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act," which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to physician payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as the ownership and investment interests of physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and/or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry;
- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs;
- HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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 significant 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, 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 United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal health care programs.

Risks Related to Intellectual Property

We depend on intellectual property licensed from third parties, in particular from Johns Hopkins, 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. Any termination of these licenses, in particular from Johns Hopkins, could result in the loss of significant rights and could harm our ability to commercialize our product candidates. See the sections of this Annual Report on Form 10-K captioned "Business—Intellectual Property" and "Business—Johns Hopkins License Agreement" for additional information regarding our license agreements.

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

- 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 license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by 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, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce patents and patent applications that are material to our business.

While we have significant control over the filing, prosecution, and maintenance of our patents licensed from Johns Hopkins, our filing, prosecution, and maintenance of these licensed patents is subject to approval of the licensor. We generally have the first right to enforce our patent rights, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of such license agreements, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control.

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

We own or license from third parties certain intellectual property rights necessary to develop our product candidates. The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that 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 larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our products or product candidates.

We anticipate that we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when any 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 others will apply for or 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 to defend our patent rights, 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 protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States 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 and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. 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. Many of our issued patents cover methods for making our cell therapy products. Method of making patents protect the process by which a product is made. This type of patent does not prevent a competitor from marketing a product that is similar to our product, if the competitor's product is made by a process not covered by our patents.

The strength of patents in the biotechnology and pharmaceutical field can be uncertain, and evaluating the scope of such patents involves complex legal and scientific analyses. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates, methods of making our product candidates, or uses thereof in the United States 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, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could 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. Because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application 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 in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, 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. Trade secrets, however, may be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, 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 United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by 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 against us or our collaborators 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, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U.S. law referred to as patent reform, procedures including inter parties review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications 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.

Although we have conducted analyses of the patent landscape with respect to our product candidates, and based on these analyses, we believe that we will be able to commercialize our product candidates, third parties may nonetheless assert that we infringe their patents, or that we are otherwise employing their proprietary technology without authorization, and may sue us. While we are aware of at least one third-party U.S. patent that is relevant to our planned products, it will expire prior to our currently planned commercial launch. There may be other third-party patents of which we are currently unaware with claims to compositions, methods of manufacture, or methods of use or treatment that cover our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies or the manufacture, use, or sale of our product candidates infringes upon these patents. If any such third-party

patents were held by a court of competent jurisdiction to cover our technologies or product candidates, the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. 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, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Third parties asserting their patent rights 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 management and other employee resources from our business, and may impact our reputation. 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. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

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

Filing, prosecuting, maintaining 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 United States can have a different scope and strength than do those in the United States. To date, in addition to the United States, we have filed patent applications in Australia, Brazil, Canada, China, Europe (via European Patent Office, or EPO), Hong Kong, India, Israel, Japan, Russian Federation, South Korea, Mexico, and Singapore. In addition, the laws of some foreign countries, such as China, Brazil, Russia, and India, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement against importation of infringing products is challenging or legal remedies are insufficient. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, such as China, Brazil, Russia, and India, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation 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. 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 involved in lawsuits 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 cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding or a declaratory judgment action against us, 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 proceeding 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.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current 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. Litigation, interference, or derivation 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.

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.

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

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 is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity 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 United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. 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 patent protection on our product candidates. Such a loss of patent protection 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 involves, both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States 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, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although 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 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.

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

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. Although 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 failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States and most foreign jurisdictions, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilars. Our issued patents will expire on dates ranging from 2034 to 2039, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2034 to 2042. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of our product candidates.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars. The Patient Protection and Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. While certain biosimilar products have been approved by the FDA for use in the United States, none of these have been cell therapy products and none have been interchangeable biosimilars. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidance is expected to be finalized by the FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that the product is "highly similar" to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and, for products administered multiple times, that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own non-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to the Commercialization of Our Product Candidates

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger-scale commercial manufacturing process for our product candidates that achieves our objectives for manufacturing capacity and cost of goods. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell our biological product candidates would adversely impact our business and future results of operations.

Our product candidates for which we intend to seek approval may face generic or biosimilar competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our AIM technology-based product candidates are expected to be regulated by the FDA as biological products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient's specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Even if we are able to commercialize any of our product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or health care reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and biological products vary widely from country to country. Current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product marketing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal health care programs or private health plans in the United States. For example, a number of cancer drugs are generally covered and paid for in the United States, but have not been approved for reimbursement in certain European countries. A primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payments for particular products. For example, payors may limit coverage to specific drug or biological products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs or biologics for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Patients are unlikely to use our products, if they are approved for marketing, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such products. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by federal health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Further, there have been, and may continue to be, legislative and regulatory proposals at the U.S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. In addition, existing legislation aimed at patient affordability in the United States such as the ACA may be repealed or replaced. The

continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

In some foreign countries, particularly the member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability for sales of any of our product candidates that are approved for marketing in that country and our business could be adversely affected.

We have no experience selling, marketing or distributing products and currently have no internal marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently have no sales, marketing or distribution capabilities and have no experience as a company in the sale or marketing of pharmaceutical products. There can be no assurance that we will be able to market and sell our products in the United States or overseas. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Therefore, with respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If so, our success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, such collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products.

If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. Further, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our products, we may in the future need to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which could be expensive, time-consuming and requiring significant attention of our executive officers to manage. Further, we may not have sufficient resources to allocate to the sales and marketing of our products.

Any failure or delay in the development of sales, marketing and distribution capabilities, through collaboration with one or more third parties or through internal efforts, would adversely impact the commercialization of any of our products that we obtain approval to market. As a result, our future product revenue will suffer and we may incur significant additional losses.

Risks Related to Our Common Stock

If we fail to maintain the listing of our common stock with a United States national securities exchange, the liquidity of our common stock could be adversely affected.

On November 30, 2023, we received a letter from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, based on Nasdaq's review of our Company and pursuant to Nasdaq Listing Rule 5101, or the Listing Rule, Nasdaq believes that we are a "public shell," and that the continued listing of our securities is no longer warranted. In response, we timely requested a hearing before a Nasdaq Hearings Panel, or the Panel, which request stayed any further action by the Staff.

Subsequent to the hearing, we received notice that the Panel had granted our request for an exception through May 28, 2024 to evidence compliance with the Listing Rule.

This compliance date represents the full extent of the Panel's discretion to grant continued listing while we are non-compliant with the Listing Rule. The Panel reserves the right to reconsider the terms of this exception based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make our continued listing inadvisable or unwarranted. Accordingly, there can be no assurance that we will be able to regain compliance with the Nasdaq listing rules or maintain our listing on the Nasdaq Capital Market. If our common stock is delisted, it could be more difficult to buy or sell our common stock or to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting could also impair our ability to raise capital.

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

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section and many others beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- any delay in identifying and advancing a clinical candidate for our other programs;
- 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, suspensions or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- changes in laws or regulations applicable to any of our product candidate, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of any 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;
- 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 product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- 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;
- the financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, Israel and Gaza, terrorism or other geopolitical events.
- sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability; and
- other events or factors, many of which are beyond our control.

In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

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. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our executive officers, directors and principal stockholders and their affiliates, if they choose to act together, will continue to have the ability to exercise significant influence over all matters submitted to stockholders for approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing a majority of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change in control;
- entrenching our management and the board of directors;
- impeding a merger, consolidation, takeover or other business combination involving us that other stockholders may desire; and/or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

We are an emerging growth company, or EGC, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we complete the IPO, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (a) the last day of the fiscal year (i) following the fifth anniversary of the completion of the IPO, (ii) in which we have total annual gross revenue of at least $2.35 billion or (iii) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as

of the prior June 30th, and (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds from the IPO was less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Annual Report on Form 10-K. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We have identified a material weakness in our internal control over financial reporting related to our control environment. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis.

In connection with the preparation of this Annual Report on Form 10-K, we identified a material weakness in our internal control over financial reporting related to our control environment. More specifically, we have determined that we have not maintained adequate segregation of duties as a result of a lack of sufficient finance and accounting staff to maintain policies and procedures intended to ensure appropriate segregation of duties with respect to accounting and financial reporting. This lack of sufficient finance and accounting staff is a consequence of our previously reported reduction-in-force. The process of designing and implementing an effective accounting and financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain an accounting and financial reporting system that is adequate to satisfy our reporting obligations. We may determine to take actions to address these control deficiencies, however, we cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weakness we have identified or avoid potential future material weakness.

Any failure to remediate the material weakness we identified or develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to remediate the material weaknesses we identified or implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

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.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of

additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

As of December 31, 2023, there are 1,066,320 shares of common stock outstanding. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

We have registered on Form S-8 all shares of common stock that are issuable under our 2021 Equity Incentive Plan. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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, or certificate of incorporation, and amended and restated bylaws, or 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 board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- 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 General Corporation Law of the State of Delaware, 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 certificate of incorporation and 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.

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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our Company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company 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.

Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by 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 bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws (in each case, as they may be amended from time to time) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided, however, that this exclusive forum provision will not apply to any causes of action arising under Exchange Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, the United States District Court for the District of Maryland will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, or the Securities Act. We have chosen the United States District Court for the District of Maryland as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Gaithersburg, Maryland. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the State of Maryland, as applicable. Additionally, the forum selection clause in our bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware or the United States District Court for the District of Maryland may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Because the applicability of the exclusive forum provision is limited to the extent permitted by applicable law, we do not intend that the exclusive forum provision would apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We also acknowledge that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and that there is uncertainty as to whether a court would enforce an exclusive forum provision for actions arising under the Securities Act.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules, and any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Risks Related to the Proposed Dissolution and Liquidation

Our proposed dissolution and liquidation may not be completed in a timely manner or at all.

As previously disclosed, on November 2, 2023, our board of directors unanimously approved the liquidation and wind up of our Company through a dissolution pursuant to a plan of liquidation and dissolution, or the Plan of Dissolution, subject to stockholder approval, while continuing to pursue alternatives intended to maximize the value of our business and our assets. We called a special meeting of the stockholders, or the Special Meeting, to seek approval of the plan of dissolution and filed proxy materials relating to the Special Meeting with the SEC as soon as practicable. As a result of the financing consummated on February 6, 2024 resulting in gross proceeds to us of approximately $3.7 million before deducting the placement agent fee and related offering expenses, we determined to postpone the Special Meeting. Subject to the outcome of our pursuit of alternatives to maximize the value of the business and our assets, we expect to call a new Special Meeting of stockholders to seek approval of the plan of dissolution, set a new record date for the determination of stockholders entitled to vote at the Special Meeting, and file proxy materials relating to the Special Meeting with the SEC.

If our stockholders do not approve the Plan of Dissolution, we would not be able to continue our business operations.

If we call a new Special Meeting and our stockholders do not approve the Plan of Dissolution, our board of directors will continue to explore what, if any, alternatives are available for the future of our Company in light of its business activities; however, those alternatives are likely limited to seeking voluntary dissolution at a later time with potentially diminished assets or seeking bankruptcy protection (should our net assets decline to levels that would require such action). It is unlikely that these alternatives would result in greater stockholder value than the proposed Plan of Dissolution.

Our board of directors may determine not to proceed with the dissolution.

If we call a new Special Meeting and the dissolution is approved by our stockholders, our board of directors may determine in its sole discretion not to proceed with the dissolution. If our board of directors elects to pursue any alternative to the Plan of Dissolution, our stockholders may not receive any of the funds that might otherwise be available for distribution to our stockholders. After the Certificate of Dissolution has been filed, revocation of the dissolution would require stockholder approval under Delaware law.

Our stockholders of record will not be able to buy or sell shares of our common stock after we close our stock transfer books at the effective time of the dissolution.

If our board of directors determines to proceed with the dissolution, we intend to close our stock transfer books and discontinue recording transfers of our common stock at the effective time of the dissolution. After we close our stock transfer books, we will not record any further transfers of our common stock on our books except by will, intestate succession or operation of law. Therefore, shares of our common stock will not be freely transferable after the effective time of the dissolution. As a result of the closing of the stock transfer books, all liquidating distributions in the dissolution, if any, will likely be made pro rata to the same stockholders of record as the stockholders of record as of the final record date.

We cannot assure you as to the amount of distributions, if any, to be made to our stockholders.

At present, we cannot predict with certainty the amount of distributions to our stockholders if the Plan of Dissolution is implemented. The amount of cash ultimately distributed to our stockholders in any distribution pursuant to the Plan of Dissolution depends on, among other things, the amount of our liabilities, obligations and expenses and claims against us, and the amount of the reserves that we establish during the liquidation process. Estimates of these amounts may be inaccurate. Factors that could impact these estimates include the following: (i) if any of the estimates regarding the Plan of Dissolution, including the expenses to satisfy outstanding obligations, liabilities and claims during the liquidation process, are inaccurate, (ii) if litigation is brought against us or our directors and officers, if unforeseen claims are asserted against us, we will have to defend or resolve such claims or establish a reasonable reserve before making distributions to our stockholders, (iii) if the estimates regarding the expenses to be incurred in the liquidation process, including expenses of personnel required and other operating expenses (including legal, accounting and other professional fees) necessary to dissolve and liquidate the Company, are inaccurate and (iv) if we continue to incur significant expenses related to ongoing reporting obligations.

General Risk Factors

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

As a public company, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. Sarbanes-Oxley, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing

uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Our issuance of additional capital stock in connection with potential future financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Cybersecurity.

We recognize the critical importance of maintaining the trust and confidence of customers, contractors, commercial partners, vendors, consultants and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes and practices are based on recognized frameworks established by the National Institute of Standards and Technology, or NIST and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We employ a range of tools and services, including regular network and endpoint monitoring, audits, vulnerability assessments, penetration testing, threat modeling and tabletop exercises to inform our risk identification and assessment. As discussed in more detail under “Cybersecurity Governance” below, our board of directors provides oversight of our cybersecurity risk management and strategy processes, which are led by our Vice President, Corporate Controller.

We also identify our cybersecurity threat risks by comparing our processes to standards set by the NIST, as well as by engaging experts to attempt to infiltrate our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls;
- conduct cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data;

- leverage the NIST incident handling framework to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident; and
- carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation. As part of the above processes, we rely on internal resources rather than consultants, auditors or other third parties, to review our cybersecurity program.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers or who have access to patient and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data, and continually monitor cybersecurity threat risks identified through such diligence.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "*Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches*," which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. In general, our board of directors oversees risk management activities designed and implemented by our management, and considers specific risks, including, for example, risks associated with our strategic plan, business operations, and capital structure. Our board of directors executes its oversight responsibility for risk management both directly and through delegating oversight of certain of these risks to its committees.

Upon detection of a material cybersecurity threat, our board of directors receives an update from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our board of directors generally receives materials that include cybersecurity materials discussing current material cybersecurity threat risks, and describing our ability to mitigate those risks, and discusses such matters with our Chief Executive Officer. Our board of directors receive prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Vice President, Corporate Controller and supported by consultants with experience in managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs as needed. These management team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, these management team members report to our board of directors about material cybersecurity threat risks.

Item 2. Properties.

Our headquarters is located in Gaithersburg, Maryland, where we leased a total of approximately 22,800 square feet of office and laboratory space under a lease that terminated on January 31, 2024. On January 31, 2024, we amended the arrangement to lease 5,377 square feet on a month-to-month basis.

We leased an additional 6,440 square feet of office space in Gaithersburg, Maryland that expired February 29, 2024.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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

On February 12, 2021, our common stock began trading on The Nasdaq Capital Market under the symbol "NEXI." Prior to that time, there was no public market for our common stock.

Holders of Our Common Stock

As of December 31, 2023, there were approximately 91 holders of record of shares of our common stock.

Dividends

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, our financial condition, our capital requirements, general business conditions, our future prospects and other factors that our board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Recent Sales of Unregistered Equity Securities

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

Issuer Purchases of Equity Securities

Not applicable.

Item 6. [Reserved.]

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this filing on Form 10-K and our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act on February 11, 2021, or the Prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Investors and others should note that we routinely use the Investor Relations section of our website to announce material information to investors and the marketplace. While not all of the information that we post on the Investor Relations section of our website is of a material nature, some information could be deemed to be material. Accordingly, we encourage investors, the media, and others interested in us to review the information that it shares on the Investor Relations section of our website, www.neximmune.com.

Overview

We are a clinical stage biotechnology company developing a novel approach to immunotherapy designed to employ the body's own T cells to generate an antigen-specific cell-mediated immune response with curative potential for the patient. Our mission is to create therapies with curative potential for patients with cancer and other life-threatening immune-mediated diseases.

On October 31, 2023, our Board of Directors approved a reduction-in-force of substantially all of our employees, other than key members of management necessary to implement the wind up and support the efforts to maximize the value of our business and our assets. As part of this strategy, we focused on developing AIM INJ nanoparticle constructs and modalities for potential clinical evaluation in oncology and autoimmune disorders. We also paused development of our current adoptive cell therapy, or AIM ACT, product candidates, NEXI-001 and NEXI-003, and the NEXI-002 trial in Multiple Myeloma. We intend to continue to explore external opportunities that may permit us to continue to advance these clinical programs.

The backbone of our approach is our proprietary Artificial Immune Modulation, or AIM. One of the critical advantages of the AIM technology platform is the ability to rapidly customize it for new therapeutics, in a modular, Lego-like manner. NexImmune has developed protein conjugation techniques so that nanoparticles can be customized quickly for different antigens, HLA alleles and Signal 2 messages. It is even possible to add additional signals or homing proteins. This gives the platform tremendous flexibility and application in oncology and infectious disease (where up-regulatory messages are delivered to targeted T cells) but also autoimmune disorders (where down-regulatory or apoptotic messages are delivered to targeted T cells). These conjugation techniques also apply to both the ex vivo adoptive cell therapy modality, called AIM ACT, and the in vivo directly-injectable modality, called AIM INJ.

The AIM INJ modality is designed to enable AIM nanoparticles to engage CD8+ T cells directly inside the body without the need for ex vivo expansion and manufacturing, which we believe will result in a greater ease of administration and a less complex and less expensive manufacturing process. We have completed substantial non-clinical work to advance the AIM INJ modality towards a potential investigational new drug application, or IND, filing, including preparing appropriate IND-enabling experiments in support of a planned clinical program focusing on solid tumors.

We were incorporated under the laws of the State of Delaware on June 7, 2011. In June 2011, we exclusively licensed the core AIM technology from The Johns Hopkins University, or Johns Hopkins. See "Business—Johns Hopkins License Agreement" for information about this license.

To date, we have devoted substantially all of our resources to organizing and staffing our Company, business planning, raising capital, identifying and developing product candidates, enhancing our intellectual property portfolio, undertaking research, conducting preclinical studies and clinical trials, and securing manufacturing for our development programs. We do not have any products approved for sale and have not generated any revenue from product sales.

To date, we have funded our operations primarily with proceeds from private placement of convertible preferred stock, our convertible promissory notes and the IPO. In February 2021, we completed the IPO and issued and sold an aggregate 297,666 shares of common stock, which included 38,826 shares of our common stock issued pursuant to the underwriters' option to purchase additional shares, at a public offering price of $425.00 per share, for net proceeds of $114.6 million after deducting underwriting discounts and commissions and other offering costs. In the year ended December 31, 2022, we sold an aggregate of 127,396 shares through our "at-the-market" offering facility resulting in net proceeds of $5.1 million. No sales were transacted for the year ended December 31, 2023.

We have incurred significant operating losses since our inception, which are mainly attributed to research and development costs and employee payroll expense. Our net loss was $32.3 million and $62.5 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $222.6 million. Our operating losses may fluctuate significantly from quarter-to-quarter and year-to-year as a result of several factors, including the timing of our preclinical studies and clinical trials and our expenditures related to other research and development activities. We expect to continue to incur operating losses for the foreseeable future. We anticipate these losses will increase substantially as we advance our product candidates through preclinical and clinical development, develop additional product candidates and seek regulatory approvals for our product candidates. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates. In addition, if we obtain marketing approval for any product candidate, we expect to incur pre-commercialization expenses and significant commercialization expenses related to marketing, sales, manufacturing and distribution. We may also incur expenses in connection with the in-licensing of additional product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As part of our reduction-in-force announced in November 2023, we incurred $0.6 million of costs related to severance pay and other related termination benefits. Management communicated the workforce reduction in November 2023.

As of December 31, 2023, we had cash and cash equivalents of $3.2 million.

Nasdaq Delisting Notification or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing

On November 30, 2023, we received a letter from the Staff of Nasdaq notifying us that, based on Nasdaq's review of our Company and pursuant the Listing Rule, Nasdaq believes that we are a "public shell," and that the continued listing of our securities is no longer warranted. In response, we timely requested a hearing before the Panel, which request stayed any further action by the Staff. Subsequently, we received notice that the Panel had granted our request for an exception through May 28, 2024 to evidence compliance with the Listing Rule.

This compliance date represents the full extent of the Panel's discretion to grant continued listing while we are non-compliant with the Listing Rule. The Panel reserves the right to reconsider the terms of this exception based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, make our continued listing inadvisable or unwarranted. Accordingly, there can be no assurance that we will be able to regain compliance with the Nasdaq listing rules or maintain our listing on the Nasdaq Capital Market. If our common stock is delisted, it could be more difficult to buy or sell our common stock or to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting could also impair our ability to raise capital.

Components of our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all.

Research and Development Expenses

To date, our research and development expenses have related primarily to development of NEXI-001 and NEXI-002 and related clinical trials, preclinical studies and other preclinical activities related to our portfolio. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Research and development expenses also include the accrual of minimum royalties under our Johns Hopkins license.

Research and development expenses include:

- salaries, payroll taxes, employee benefits and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, and consultants to conduct our preclinical, toxicology and other preclinical studies;
- laboratory supplies;
- costs related to manufacturing product candidates, including fees paid to third-party manufacturers and raw material suppliers;
- license fees and research funding; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance, equipment and other supplies.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators and other third-party service providers to assist us with the execution of our clinical trials. We also expect to incur additional expenses related to milestone and royalty payments payable to Johns Hopkins.

As we continue the development of our product candidates and seek to discover and develop new product candidates, we will likely require substantial funds to continue such activities. Due to the inherently unpredictable nature of preclinical and clinical development, we cannot determine with certainty the timing of the initiation, duration or costs of future clinical trials and preclinical studies of product candidates. Clinical and preclinical development timelines, the probability of success and the amount of development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly based on factors such as:

- per-patient trial costs;
- the number of trials required for regulatory approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in our executive, finance and other administrative functions. Other significant costs include facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and insurance costs. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercialization activities and, if any product candidates receive marketing approval, commercialization activities if we are successful in raising funds to pursue these programs. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Interest Income

Interest income consists of interest earned on our cash equivalents and marketable securities during the period.

Interest Expense

Interest expense consists of interest accrued on the convertible notes and interest recognized upon the amortization of the beneficial conversion feature, debt issuance costs and bifurcated derivative liability.

Loss on assets held for sale

The loss on assets held for sale consists of fixed assets that ceased depreciation and measured at the lower of its carry value or fair value less cost to sell.

Results of Operations

Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022:

	For the years ended December 31,		
	2023	2022	Change
	(in thousands)		
Operating expenses:			
Research and development	19,282	$ 47,148	$ (27,866)
General and administrative	13,001	15,934	(2,933)
Loss on assets held for sale	691	—	691
Total operating expenses	32,974	63,082	(30,108)
Loss from operations	(32,974)	(63,082)	30,108
Other income (expense), net:			
Interest income	698	644	54
Other expense	(69)	(88)	19
Total other income, net	630	577	53
Net loss	$ (32,344)	$ (62,505)	$ 30,161

Research and Development Expenses. Research and development expenses were $19.3 million and $47.1 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $27.9 million was due primarily to decreases of $14.4 million on research and preclinical manufacturing, a decrease of $6.2 million on clinical trial expenses, a decrease to salary and benefits of $7.1 million resulting from decreased headcount that includes an offset of $2.9 million in restructuring charges and a $2.7 million decrease in stock compensation expense. We have not historically tracked internal research and development expenses by product candidate.

General and Administrative Expenses. General and administrative expenses were $13.0 million and $15.9 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $2.9 million was due primarily to decreases of $2.9

million in legal and professional fees, a decrease in salary and benefits of $0.2 million from decreased head count and reduction, offset by $0.2 million increase in facility costs.

Loss on assets held for sale. We designated certain equipment held for sale, ceased depreciation, and measured the held for sale assets at the lower of its carry value or fair value less cost to sell resulting in the loss on assets held for sale of equipment for the year ended December 31, 2023.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of December 31, 2023, we had cash and cash equivalents of $3.2 million.

On February 2, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with a single healthcare focused institutional investor (the "Investor"), pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market (the "Registered Offering"), (i) an aggregate of 117,000 shares (the "Shares") of common stock, par value $0.0001, of the Company (the "Common Stock"), at an offering price of $12.05 per share, and (ii) pre-funded warrants (the "Pre-Funded Warrants") exercisable for up to 187,731 shares of Common Stock (the "Pre-Funded Warrant Shares"), at an offering price of $12.049 per Pre-Funded Warrant, for aggregate gross proceeds from the Offerings (as defined below) of approximately $3.7 million before deducting the placement agent fee (as described in greater detail below) and related offering expenses. The closing of the Offerings is expected to occur on or about February 6, 2024, subject to the satisfaction of customary closing conditions.

The shares of Common Stock and Pre-Funded Warrants (and shares of common stock underlying the Pre-Funded Warrants) were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-263399), which was filed with the Securities and Exchange Commission (the "SEC") on March 9, 2022 and declared effective by the SEC on March 16, 2022 ("Registration Statement"), including the base prospectus contained therein, and a related prospectus supplement, dated February 2, 2024, filed with the SEC on February 5, 2024.

In a concurrent private placement (the "Private Placement" and, together with the Registered Offering, the "Offerings"), the Company issued to the Investor unregistered warrants to purchase up to an aggregate of 304,731 shares of Common Stock (the "Unregistered Warrants") at an exercise price of $12.05 per share. Each Unregistered Warrant is exercisable immediately and will expire two years from the initial exercise date. The Unregistered Warrants and the shares of our Common Stock issuable upon the exercise of the Unregistered Warrants are not being registered under the Securities Act of 1933, as amended (the "Securities Act"), are not being offered pursuant to the Registration Statement and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act, and/or Rule 506(b) promulgated thereunder.

We believe that our existing cash and cash equivalents will be sufficient to fund our activities into the second quarter of 2024.

As our research and development activities mature and develop over the next year, we will likely require substantial funds to continue such activities, depending upon events that are difficult to predict at this time. In this regard, management plans to raise additional capital through financing activities that may include public offerings and private placements of our common stock, preferred stock offerings, collaborations and licensing arrangements and issuances of debt and convertible debt instruments. In the absence of additional capital, the Company plans to strategically manage its uncommitted spend, execute its priorities and implement cost saving measures to reduce research and development and general and administrative expenditures which could include minimizing staff costs and delaying or terminating manufacturing and clinical trial costs. There are inherent uncertainties associated with fundraising activities and activities to manage our uncommitted spending and the successful execution of these activities may not be within our control. There are no assurances that such additional funding will be obtained and that the Company will succeed in its future operations. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected. We are continually looking into further capital planning and the evaluation of strategic alternatives. There is substantial doubt about our ability to continue as a going concern.

Sources of Liquidity

We have financed our operations principally through private placements of our convertible preferred stock, our convertible promissory notes, the IPO, and an "at-the-market" offering facility.

Initial Public Offering

In February 2021, we completed an IPO and issued and sold an aggregate 297,666 shares of common stock, which included 38,826 shares of our common stock issued pursuant to the underwriters' option to purchase additional shares, at a public offering price of $425.00 per share, for net proceeds of $114.6 million after deducting underwriting discounts and commissions and other offering costs.

"At-the-market" offering facility

During the year ended December 31, 2022, we sold an aggregate of 3,184,900 shares through our "at-the-market" offering facility resulting in net proceeds of $5.1 million. No sales were transacted for the year ended December 31, 2023.

Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2023 and 2022:

	Year ended December 31	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (31,430)	$ (51,191)
Investing activities	(44)	50,316
Financing activities	—	5,179
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (31,474)	$ 4,303

Operating Activities

Net cash used in operating activities was $31.4 million and $51.2 million for the years ended December 31, 2023 and 2022, respectively. The net cash used in operating activities for the year ended December 31, 2023 was primarily due to our net loss of $32.3 million, resulting from R&D expenditures of $19.3 million as we continue to our preclinical program and transition our clinical programs and $13.0 million of administrative expenses for salary and related expenses and professional fees. Our net loss is partially offset by $0.9 million in non-cash expenses and working capital changes.

The net cash used in operating activities for the year ended December 31, 2022 was primarily due to our net loss of $62.5 million, consisting of $47.1 million for R&D expenses primarily in pre-clinical research expenses as we prepared for our clinical program and began ramping up our clinical programs, and $15.9 million in administrative expenses for salary and related expenses and profession fees. These are partially offset by $11.3 million in non-cash expenses and working capital changes.

Investing Activities

Net cash used in investing activities was nominal for the year ended December 31, 2023.

Net cash provided by investing activities was $50.3 million for the year ended December 31, 2022. The net cash provided by investing activities for the year ended December 31, 2022 was primarily due to the maturities of $71.5 million and redemption of $1.5 million in available-for-sale marketable securities partially offset by the purchase of $21.5 million in available-for-sale marketable securities and by the purchase of property and equipment of $1.3 million.

Financing Activities

Net cash provided by financing activities was nominal for the year ended December 31, 2023.

Net cash provided by financing activities was $5.2 million for the year ended December 31, 2022 primarily due to the net proceeds of $5.1 million from the "at-the-market" offering facility.

Funding Requirements

We believe that our existing cash and cash equivalents together with follow on raise in February 2024 will be sufficient to meet our anticipated cash requirements into the second quarter of 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. If we are not able to raise additional funding, we may not be able to enter into successful collaborations under favorable terms. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business.

Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- the cost of manufacturing our product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the emergence of competing therapies and other adverse market developments;
- the ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our capital requirements, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may need to relinquish valuable rights to our product candidates, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings as and when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3, "Summary of significant accounting policies," we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Accrued Research and Development Expenses & Prepayment of Services

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract-to-contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation

We account for our stock-based compensation as expense in the statements of operations based on the awards' grant date fair values. We account for forfeitures as they occur by reversing any expense recognized for unvested awards.

For grants of restricted stock units, we base the fair value on the stock price as of the date of grant. We estimate the fair value of options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We use the simplified method as allowed by the SEC, Staff Accounting Bulletin, or SAB, No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock. The fair value of stock-based payments is recognized as expense over the requisite service period which is generally the vesting period.

Other Company Information

Net Operating Loss and Research and Development Carryforwards and Other Income Tax Information

On December 31, 2023, we had federal and state net operating loss carryforwards of $154.3 million and federal research credit carryforwards of $0.3 million. Approximately $10.5 million of the federal NOL was generated prior to 2018 and will expire in increments through 2037 beginning in 2035, while the remaining $143.8 million will be carried forward indefinitely. The state NOL will expire in increments through 2037, beginning expiring in 2035. The federal research and development tax credit carryforwards, if not utilized, will expire beginning in 2037.

We believe that it is more likely than not that we will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2023. Management reevaluates the positive and negative evidence at each reporting period.

We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional such ownership changes in the future. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss and research and development tax credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenues of at least $2.35 billion, (3) the date on which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company,

- we may present only two years of audited financial statements, plus unaudited condensed financial statements for any interim period, and related Management's Discussion and Analysis of Financial Condition and Results of Operations in this filing.
- we may avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we may not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this filing is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. Until the date that we are no longer an emerging growth company or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act of 1933 upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of the IPO was less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. After the IPO we may continue to be a smaller reporting company if either (1) the market value of our stock held by non-affiliates is less than $250.0 million or (2) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time, we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 3, "Summary of significant accounting policies."

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

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks, foreign currency exchange rate risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe have high credit quality and have not experienced any significant losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Interest Rate Risk

Our cash consists of cash in readily-available checking accounts and short-term money market fund investments. Such interest-earning instruments carry a degree of interest rate risk and the returns from such instruments will vary as short-term interest rates change. While historical fluctuations in interest income have not been significant, in a financial environment with extremely low or negative interest rates, we could experience a significant reduction in the interest earned from such instruments.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States. We have, from time-to-time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data.

The financial statements and related financial statement schedules required to be filed are listed in the Index to Financial Statements and are incorporated in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer (our principal executive officer) and our Controller (our principal financial and accounting officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Controller concluded that, as of such date, our disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting described below. In light of this fact, our management has taken additional steps to assure there is appropriate disclosure in this report and has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the financial statements for the periods covered by and included in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, under the supervision and with the participation of our Chief Executive Officer and Controller, conducted an assessment of the evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that our internal control over financial reporting was not effective as of December 31, 2023.

As previously disclosed, we identified a material weakness in our internal control over financial reporting related to our control environment during the preparation of our unaudited financial statements for the three and nine months ended September 30, 2023, which remained unremediated as of December 31, 2023. More specifically, we determined that we did not maintained adequate segregation of duties as a result of a lack of sufficient finance and accounting staff to maintain policies and procedures intended to ensure appropriate segregation of duties with respect to accounting and financial reporting. This lack of sufficient finance and accounting staff is a consequent of our previously reported reduction-in-force. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

In order to remediate this material weakness, we will need to hire additional financing and accounting staff and develop and roll out training on processes and controls. We are also considering engaging the assistance of additional third-party resources as deemed appropriate to assist management in its remediation efforts.

The process of designing and implementing an effective accounting and financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain an accounting and financial reporting system that is adequate to satisfy our reporting obligations. We may determine to take actions to address these control deficiencies, however, we cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weakness we have identified or avoid potential future material weakness.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. Additionally, our independent registered public accounting firm will not be required to opine on our internal control over financial reporting until we are no longer an emerging growth company.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting other than the material weakness described above.

Item 9B. Other Information.

During the fiscal quarter ended December 31, 2023, none of our directors or officers (as defined in Section 16 of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our Board of Directors

The following table provides information regarding our executive officers and directors as of March 1, 2024:

Name	Age	Position
Executive Officers:		
Kristi Jones	60	President, Chief Executive Officer and Director
Mathias Oelke, Ph.D.	56	Chief Science Officer
Timothy Stover	51	Vice President, Corporate Controller
Non-Employee Directors:		
Sol J. Barer, Ph.D. (2)(3)	76	Chairperson of the Board of Directors
Alan S. Roemer, M.B.A., M.P.H. (1)	54	Director
Tim Bertram, Ph.D. (1)(2)	68	Director
Paul D'Angio, R.P.H., M.S.J. (1)(2)	65	Director
Zhengbin (Bing) Yao, Ph.D. (3)	58	Director
Grant Verstandig (3)	34	Director
Leena Gandhi, M.D., Ph.D.	53	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Governance Committee.

Executive Officers

Kristi Jones has served as our President and Chief Executive Officer and as a member of our board of directors since February 2022. She served as our Chief Operating Officer from March 2018 to February 2022, our Chief Business Officer from June 2017 to March 2018, and as a consultant to the Company from September 2015 to February 2017. Prior to joining us, from 2013 to 2015, Ms. Jones served as Vice President of Portfolio Strategy at AstraZeneca. From November 2011 to July 2013, she served as Vice President of Global Strategic Marketing at MedImmune. Prior to that, Ms. Jones held multiple leadership roles with increasing responsibility at Genentech where she worked for 16 years, including Head of Immunology and Ophthalmology Global Product Strategy, Life Cycle Lead and Franchise Management. Ms. Jones has held roles in Strategy, Business Development, Commercial Operations, Managed Care, Marketing and Sales. Ms. Jones serves on the Life Science Panel for Springboard Enterprises focused on start-up companies led by women and on the Cell Therapy Committee for the Alliance of Regenerative Medicine. Ms. Jones received her Pharmacy degree from the University of Texas, College of Pharmacy and her B.S. in Biology from Texas Tech University. We believe that Ms. Jones' qualifications to serve on the board of directors include her extensive executive leadership in the life sciences industry and her knowledge of our business, having previously served in several senior positions with the company.

Mathias Oelke, Ph.D. has served as our Chief Scientific Officer since April 2022. Dr. Oelke has more than 20 years of research experience in cancer immunotherapy and has a long-standing track record of developing methods for antigen-specific stimulation of T cells for therapeutic use. Prior to his promotion, he served as Senior Vice President, Preclinical Immunotherapy and Head of Cell Biology of NexImmune since 2017. Dr. Oelke has numerous peer-reviewed publications and is a co-inventor on more than 25 patents and patent applications describing NexImmune's proprietary aAPC technology, with additional pending patent applications in related fields of cancer immunotherapy. Previously, he was a member of the faculty at the Johns Hopkins University for over 11 years. Dr. Oelke, who is a chemist by training, received his Ph.D. in Biology from University of Freiburg, where he first became interested in the critical role of antigen presenting cells and their use in immunotherapy.

Timothy Stover has served as our Vice President, Corporate Controller since in June 2021. In August 2023, he was also appointed our principal financial and accounting offer. From 2018 to 2021, Mr. Stover served as Executive Director, Corporate Controller, at Autolus Therapeutics Plc., a publicly traded, clinical-stage pharmaceutical company. From 2017 to 2018, Mr. Stover served as Director, Financial Reporting for Sucampo Pharmaceuticals, Inc., and from 2014 to 2017, as Associate Director of External Reporting & Technical Accounting at Iridium Communications Inc. Prior to that, Mr. Stover worked as a

Senior Manager at Ernst & Young LLP. Mr. Stover received B.A. in Economics from Wittenberg University and an MPA from American University and is a Certified Public Accountant in the State of Virginia.

Non-Employee Directors

Sol J. Barer, Ph.D. has served as the Chairperson of our board of directors since November 2019. Dr. Barer has served as Chairperson of the Hackensack Meridian Health Center for Discovery & Innovation, a research center, since June 2018 and as a member of Barer & Son Capital, an investment fund focused on capitalizing early-stage breakthrough biotechnology companies, since 2017. Dr. Barer also serves on the boards of directors of several public companies, including Teva Pharmaceutical Industries Limited as Chairperson and ContraFect Corporation as lead Director. Dr. Barer previously served as Chairperson and director of InspireMD, Inc. from 2011 to 2017, and as a director of Amicus Therapeutics, Inc. from 2009 to 2017 and Aegerion Pharmaceuticals, Inc. from 2011 to 2016. From 1987 to 2011, Dr. Barer held various leadership positions at Celgene. He served as Chairperson of Celgene from January 2011 to June 2011, Executive Chairperson from June 2010 to January 2011, and Chairperson and Chief Executive Officer from May 2006 to June 2010. He was previously President of Celgene from 1993 to May 2016 and Chief Operating Officer from 1994 to May 2006. Dr. Barer was the founder of the biotechnology group at the Celanese Research Company that was subsequently spun off as Celgene. Dr. Barer also served as the Chairperson and director of Edge Therapeutics from 2011 to 2019 and as the Chairperson of Aevi Genomic Medicine from 2012 to 2021. Dr. Barer received his Ph.D. in organic and physical chemistry from Rutgers University and his B.S. in chemistry from Brooklyn College of the City University of New York. We believe that Dr. Barer's qualifications to serve on our board of directors include his significant scientific, executive and board leadership experience in the biopharmaceutical industry.

Alan S. Roemer, M.B.A., M.P.H. has served as a member of our board of directors since February 2017 and served as Chairperson of our board of directors from December 2017 to November 2019. He has served as Chairperson and a member of the board of directors of IN8bio, Inc., a public biotechnology company, since September 2020; Chairperson and a member of the board of directors of UTILITY therapeutics Ltd., a private biotechnology company, since March 2020; a member of the board of directors of Bit. Bio Ltd., a private synthetic biology company, since August 2021; and a member of the board of trustees of the Helene Fuld College of Nursing since June 2014. Mr. Roemer was a founding leadership team member and senior vice president of Roivant Sciences, Inc., a private biopharmaceutical company, from the company's inception May 2014 to August 2019, where he held various senior management roles responsible for finance, operations and corporate development. From March 2015 to August 2015, he also served as principal financial and accounting officer of Axovant Sciences Ltd., a public biopharmaceutical company, and a founding leadership team member and chief financial officer of its wholly owned subsidiary, Axovant Sciences, Inc. Prior to Roivant and Axovant, Mr. Roemer served in various executive roles, including managing director of the Trout Group LLC and Trout Capital LLC from 2009 to 2014, chief financial officer and treasurer of Zelos Therapeutics, Inc. from 2008 to 2009, and vice president of Pharmasset, Inc. 1999 to 2008, which was subsequently acquired by Gilead Sciences, Inc. Mr. Roemer has also served as a member of the board of directors of Envisagenics, Inc., a private artificial intelligence company, from September 2021 to February 2023, and as a member of the board of directors of SomPharmaceuticals SA, a private biopharmaceutical company, from August 2012 to May 2016, until its acquisition by Amryt Pharma plc. Mr. Roemer received a B.S. in Business Administration from Georgetown University and his MBA and MPH degrees from Emory University's Goizueta Business School and Rollins School of Public Health. We believe that Mr. Roemer's qualifications to serve on our board include significant executive and board leadership experience in the biopharmaceutical industry.

Tim Bertram, Ph.D. has served as a member of our board of directors since January 2017. Dr. Bertram currently serves as Chief Executive Officer of the National Science Foundation, Regional Innovation Engine of North Carolina, and Partnership Program Director, Wake Forest Institute for Regenerative Medicine, Wake Forest University School of Medicine. From May 2020 to November 2023, Dr. Bertram served as Chief Executive Officer and board member of ProKidney, a late clinical-stage biotech company. From 2016 to 2019, Dr. Bertram served as Chief Executive Officer and as a member of the board of directors of inRegen, a clinical-stage cellular therapeutics company focused on the treatment of chronic renal disease. Mr. Bertram also is a member of the board of directors of Twin City Bio LLC, a contract development and manufacturing service for pharmaceutical and biotech companies focused on cell-based therapies. Prior to that, he served as Chief Executive Officer of RegenMed Therapeutics. He served as Chief Scientific Officer of Tengion Inc. from 2004 to 2014 after serving as President of Research and Development where he brought four cell-based therapeutic products from discovery through Phase 2 clinical development. Dr. Bertram was involved in the development and registration of eight medical products while serving as a senior executive at Pfizer Inc., SmithKline Beecham Pharmaceuticals, and The Procter & Gamble Company. He was a faculty member at the University of Illinois, and a visiting scientist at the National Institutes of Health. Tengion Inc. filed a voluntary chapter 7 bankruptcy petition in December 2014. Dr. Bertram received his D.V.M. and Ph.D. in Cellular Pathology from Iowa State University and was board certified in Veterinary Pathology in 1984. We believe that Dr. Bertram's qualifications to serve on our board of directors include his leadership experience in drug development at public and private biotechnology companies, along with his leadership in the innovation of cellular therapeutics.

Paul D'Angio, R.P.H., M.S.J. has served as a member of our board of directors since January 2017. Mr. D'Angio has served as President of PDA Pharmaceutical Services LLC, a pharmaceutical manufacturing consultancy, since September 2016.

Mr. D'Angio also served as Vice President, Head of Manufacturing of PDS Biotechnology Corporation, a clinical-stage immunotherapy company, from March 2019 through June 2020. From December 2017 to March 2019, Mr. D'Angio served as Vice President, Head of Development of Edge Therapeutics, Inc., a biopharmaceutical company. From December 1998 to August 2016, he served as Senior Director, Senior Vice President, Global Head of Technical Operations of Celgene, where he gained extensive cross-functional and technical leadership experience in building and operating a global pharmaceutical manufacturing and supply chain organization. Mr. D'Angio is a registered pharmacist and received his BSc in Pharmacy from Duquesne University and MSJ in Healthcare Law from Seton Hall University Law School. We believe that Mr. D'Angio's qualifications to serve on our board of directors include his substantial experience in the pharmaceutical industry, specifically in commercial manufacturing, drug product development, risk management operations and investigational materials supply.

Zhengbin (Bing) Yao, Ph.D. has served as a member of our board of directors since January 2017. Dr. Yao brings more than 20 years' experience in the biopharmaceutical industry. Since June 2021, Dr. Yao has served as chief executive officer and Chairperson of ArriVent BioPharma, a biotechnology company focused on the development of biopharmaceutical products. From February 2018 to March 2021, Dr. Yao served as Chief Executive Officer of Viela Bio, Inc., a clinical-stage biotechnology company focused on autoimmune and severe inflammatory diseases and as Chairperson of its board of directors from January 2019 to March 2021. From October 2010 to February 2018, Dr. Yao served in various leadership roles at MedImmune, most recently as Senior Vice President, Head of Respiratory, Inflammation, Autoimmune iMED. Dr. Yao also served as Senior Vice President, Head of Immuno-Oncology Franchise, of AstraZeneca. Prior to his tenure at MedImmune and AstraZeneca, Dr. Yao served as Head of PTL for Immunology, Infectious Diseases, Neuroscience, and Metabolic Disease of Genentech. Previously, Dr. Yao was Vice President and Head of Research of Tanox, Inc., before it was acquired by Genentech in 2007. Dr. Yao serves on the board of directors of Immune-Onc Therapeutics, Inc., a private biotechnology company developing biotherapies for cancer. Dr. Yao received his M.S. in Immunology from Anhui Medical University in Anhui, China and his Ph.D. in Microbiology and Immunology from the University of Iowa. We believe that Dr. Yao's qualifications to serve on our board of directors include his significant experience in the biopharmaceutical industry, particularly in autoimmune disease, and his experience serving as a chief executive officer of a publicly-traded biotechnology company.

Grant Verstandig has served as a member of our board of directors since January 2021. Since October 2020, Mr. Verstandig is a Co-Founder serves as the Chairperson of Red Cell Partners, an investment and incubation firm that backs, builds, and scales early-stage technology-led companies in the healthcare and national security sectors. Mr. Verstandig was the founder and served as the chief executive officer of Rally Health, Inc., a consumer centric digital health company acquired by UnitedHealth Group from January 2010 to April 2022. He has also served as the Executive Chairperson of Epirus, a venture-backed directed energy company that creates counter-UAS systems and power management solutions for multiple applications from since November 2022 and served as Executive Chairperson from June 2018 to April 2022. Since April 2021, Mr. Verstandig is a co-founder and serves as the Executive Chairperson of Zephyr AI Inc., an artificial intelligence platform of precision medicine and drug discovery. Mr. Verstandig also co-founded Spycraft Entertainment, a content and entertainment production company focused on intelligence and military operations, in June 2018. Mr. Verstandig has also served on the National Council for the American Enterprise Institute since April 2016 and is a founding member of the Greater Washington Partnership, where he has been a director since January 2017. Mr. Verstandig has served as an advisor to several organizations in the health, defense, foreign policy and intelligence spaces, and has served as a senior advisor to the National Security Agency on advanced analytics, technology and artificial intelligence since 2017. Mr. Verstandig attended Brown University. We believe that Mr. Verstandig's qualifications to serve on our board of directors include his healthcare industry experience, along with his leadership in the innovation of technology-enabled health services.

Leena Gandhi has served as a member of our board of directors since May 2022. Dr. Gandhi has served as the Chief Medical Officer of NextPoint Therapeutics since January 2023. She has served as Director of the Center for Cancer Therapeutic Innovation at the Dana-Farber Cancer Institute from June 2020 until January 2023; and previously served and prior to that as Vice President of Immuno-Oncology Development at Eli Lilly from June 2018 to May 2020, where she led the development of novel immune-oncology agents across cancer types. From June 2016 to June 2018, Dr. Gandhi served as the Director of Thoracic Medical Oncology at New York University where she focused her research on novel drug development and biomarkers for selection in lung cancer with a particular focus on immuno-oncology. Dr. Gandhi received her Ph.D. from the University of California, Berkeley, and her M.D. from New York University, and her B.S. from the University of Utah, Salt Lake City. Dr. Gandhi completed her postgraduate training at Massachusetts General Hospital in addition to Dana-Farber Cancer Institute in Boston, where she was later a clinical fellow and faculty member in the Thoracic Oncology program. Dr. Gandhi's qualifications to serve on the board of directors include her significant experience as a clinical investigator and medical professional and her insight and expertise with respect to clinical trials and drug development.

Board Composition

As of March 1, 2024, our board of directors consisted of eight members, all of whom are members pursuant to the board composition provisions of our existing certificate of incorporation. Our board of directors may consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to

race, gender or national origin. We have no formal policy regarding board diversity. Our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal. Our certificate of incorporation and amended and restated by-laws provides that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director Independence

Rule 5605 of the Nasdaq Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the board of directors, the audit committee or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has determined that all members of our board of directors, except Kristi Jones, are independent directors, including for purposes of the rules of The Nasdaq Stock Market and relevant federal securities laws and regulations. There are no family relationships among any of our directors or executive officers.

Staggered Board

Our board of directors is divided into three staggered classes of directors of the same or nearly the same number, and each is assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2025 for Class I directors, 2026 for Class II directors, and 2024 for Class III directors:

- our Class I directors are Mr. D'Angio and Dr. Zhengbin (Bing) Yao;
- our Class II directors are Mr. Roemer, Dr. Bertram and Mr. Verstandig; and
- our Class III directors are Dr. Barer, Ms. Jones and Dr. Gandhi.

Committees of Our Board of Directors and Meetings

Audit committee. Our Audit committee has three members, Alan S. Roemer (Chairperson), Tim Bertram, and Paul D'Angio. Our board of directors has determined that each member of the Audit committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq Listing Rules and has sufficient knowledge in financial and auditing matters to serve on the Audit committee. Our board of directors has determined that Alan S. Roemer is an "audit committee financial expert," as the Securities and Exchange Commission has defined that term in Item 407 of Regulation S-K. The Audit committee's responsibilities include:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;

- considering the effectiveness of our internal controls and internal audit function;
- reviewing material related-party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

A copy of the Audit committee's written charter is publicly available on our website at *https://ir.neximmune.com/investors/corporate-governance*.

Compensation committee. Our Compensation committee has three members, Tim Bertram (Chairperson), Sol Barer, and Paul D'Angio. Our Compensation committee's role and responsibilities are set forth in the Compensation committee's written charter and includes reviewing, approving and making recommendations regarding our compensation policies, practices and procedures to ensure that legal and fiduciary responsibilities of our board of directors are carried out and that such policies, practices and procedures contribute to our success. Our Compensation committee also administers our 2021 Equity Incentive Plan. The Compensation committee is responsible for recommending to our board of directors the compensation for our chief executive officer and conducts its deliberations or voting with respect to that issue without the chief executive officer present. All members of the Compensation committee qualify as independent under the definition promulgated by the Nasdaq Listing Rules.

Generally, the Compensation committee's process involves the establishment of corporate goals and objectives for the current year and determination of compensation levels. For executives other than the Chief Executive Officer, the compensation committee solicits and considers evaluations and recommendations submitted to the committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation is conducted by the Compensation committee, which recommends any adjustments to his compensation levels and arrangements for approval by the board of directors.

The Compensation committee has the sole authority to obtain, at our expense, advice and assistance from compensation consultants, legal counsel, experts and other advisors that the Compensation committee deems advisable in the performance of its duties. The Compensation committee has the sole authority to approve any such consultants' or advisors' fees and other retention terms. The Compensation committee may select any such consultant, counsel, expert or adviser to the Compensation committee, only after taking into consideration factors that bear upon the adviser's independence. The Compensation committee's independent compensation consultant during fiscal year ended December 31, 2023 was AON Consulting, or AON, AON is engaged by, and reports directly to, the Compensation committee, which has the sole authority to hire or fire AON and to approve fee arrangements for work performed. AON assists the Compensation committee in fulfilling its responsibilities under its charter, including advising on proposed compensation packages for executive officers, compensation program design and market practices generally. The Compensation committee has authorized Radford to interact with management on behalf of the Compensation committee, as needed in connection with advising the Compensation committee, and AON is included in discussions with management and, when applicable, the Compensation committee's outside legal counsel on matters being brought to the Compensation committee for consideration.

A copy of the Compensation committee's written charter is publicly available on our website at *https://ir.neximmune.com/investors/corporate-governance*.

Nominating and Governance committee. Our Nominating and Governance committee, or Nominating Committee, has three members, Sol Barer, Ph.D. (Chairperson), Zhengbin (Bing) Yao, Ph.D., and Grant Verstandig. Our board of directors has determined that all members of the Nominating Committee qualify as independent under the definition promulgated by the Nasdaq Stock Market. The Nominating Committee's responsibilities are set forth in the Nominating Committee's written charter and include:

- evaluating and making recommendations to the full Board as to the composition, organization and governance of our board of directors and its committees,
- evaluating and making recommendations as to director candidates,
- evaluating current Board members' performance
- overseeing the process for Chief Executive Officer and other executive officer succession planning, and
- developing and recommending governance guidelines for the Company.

Generally, our Nominating Committee considers candidates recommended by stockholders as well as from other sources such as other directors or officers, third party search firms or other appropriate sources. Once identified, the Nominating Committee will evaluate a candidate's qualifications in accordance with our Nominating and Governance Committee Policy

Regarding Qualifications of Directors appended to our Nominating Committee's written charter. Threshold criteria include: personal integrity and sound judgment, business and professional skills and experience, independence, knowledge of our industry, possible conflicts of interest, diversity, the extent to which the candidate would fill a present need on our board of directors, and concern for the long-term interests of our stockholders. Our Nominating Committee has not adopted a formal diversity policy in connection with the consideration of director nominations or the selection of nominees. However, the Nominating Committee will consider issues of diversity among its members in identifying and considering nominees for director and strive where appropriate to achieve a diverse balance of backgrounds, perspectives, experience, age, gender, ethnicity and country of citizenship on our board of directors and its committees.

If a stockholder wishes to propose a candidate for consideration as a nominee for election to our board of directors, it must follow the procedures described in our bylaws. In general, persons recommended by stockholders will be considered in accordance with our Policy on Stockholder Recommendation of Candidates for Election as Directors appended to our Nominating Committee's written charter. Any such recommendation should be made in writing to the Nominating and Governance Committee, care of our Corporate Secretary at our principal office and should be accompanied by the following information concerning each recommending stockholder and the beneficial owner**,** if any, on whose behalf the nomination is made:

- all information relating to such person that would be required to be disclosed in a proxy statement;
- certain biographical and share ownership information about the stockholder and any other proponent, including a description of any derivative transactions in the Company's securities;
- a description of certain arrangements and understandings between the proposing stockholder and any beneficial owner and any other person in connection with such stockholder nomination; and
- a statement whether or not either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of voting shares sufficient to carry the proposal.

The recommendation must also be accompanied by the following information concerning the proposed nominee:

- certain biographical information concerning the proposed nominee;
- all information concerning the proposed nominee required to be disclosed in solicitations of proxies for election of directors;
- certain information about any other security holder of the Company who supports the proposed nominee;
- a description of all relationships between the proposed nominee and the recommending stockholder or any beneficial owner, including any agreements or understandings regarding the nomination; and
- additional disclosures relating to stockholder nominees for directors, including completed questionnaires and disclosures required by our bylaws.

A copy of the Nominating Committee's written charter, including its appendices, is publicly available on our website at *https://ir.neximmune.com/investors/corporate-governance*.

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation committee has at any time during the last fiscal year been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or Compensation committee of any entity that has one or more executive officers serving on our board of directors or Compensation committee. For a description of transactions between us and members of our Compensation committee and affiliates of such members, please see the "Certain Relationships and Related Party Transactions" section of this Annual Report on Form 10-K.

Board Leadership Structure

The positions of our chairperson of the board and chief executive officer are separated, with Ms. Jones serving as our Chief Executive Officer and Dr. Barer serving as the chairperson of our board of directors. Separating these positions allows Ms. Jones, as our Chief Executive Officer, to focus on our day-to-day business, while allowing the chairperson of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that Ms. Jones, as our Chief Executive Officer, must devote to her position in the current business environment, as well as the commitment of a member of our board of directors required to serve as our

chairperson, particularly as the board of directors' oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of our Company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure. Our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Role in Risk Oversight

Our board of directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our board of directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our board of directors addresses the primary risks associated with those operations and corporate functions. In addition, our board of directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of our risks that fall within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Executive Officer reports risk management controls and methodologies to the Audit committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our Audit committee meets privately with representatives from our independent registered public accounting firm and our Chief Executive Officer. The Audit committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our board of directors regarding these activities.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees. The text of the code of business conduct and ethics is posted on the "Investor Relations — Corporate Governance" section of our website at *https://ir.neximmune.com/investors/corporate-governance*. We intend to disclose any amendments to, or waivers from, provisions of the code of business conduct and ethics that apply to our directors, principal executive and financial officers in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by Nasdaq rules.

Item 11. Executive Compensation.

Summary Compensation Table

The following table shows the total compensation paid or accrued during the last two fiscal years ended December 31, 2023 and 2022 to our Chief Executive Officer and President, our two next most highly compensated executive officers and our Chief Financial Officer, each of whom earned more than $100,000 during the fiscal years ended December 31, 2023 and 2022, and was serving as an executive officer as of such date.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Kristi Jones	2023	675,102	285,450	93,537	28,727	1,082,816
President and Chief Executive Officer	2022	511,824	148,800	1,471,843	19,819	2,152,286
John Trainer (4)	2023	728,722	217,098	27,780	15,971	989,571
Chief Financial Officer	2022	384,292	146,000	285,068	15,842	831,202
Jerome Zeldis (5)	2023	137,452	158,415	—	14,282	310,149
EVP, Head of Research & Development	2022	398,927	173,250	234,586	46,022	852,785
Mathias Oelke (6)	2023	416,333	153,386	25,286	36,057	631,062
Chief Science Officer	2022	352,713	115,500	232,465	35,594	736,272
Timothy Stover (7)	2023	273,453	76,720	9,977	10,505	370,655
Vice President, Corporate Controller						

(1) The amount represents bonuses earned for 2021 and 2022 then paid in 2023 and 2022, respectively.
(2) These amounts represent the aggregate grant date fair value for option granted and RSUs awarded during the fiscal years ended December 31, 2023 and 2022, computed in accordance with FASB ASC Topic 718.
(3) The amounts in this column include our 401(k) match contribution for each named executive officer, medical insurance for Mr. Zeldis, and life insurance premium paid for Mr. Oelke.
(4) Mr. Trainer was terminated through a reduction-in-force in August 2023.
(5) Mr. Zeldis joined the Company in 2021. On March 23, 2023, Mr. Zeldis resigned as EVP, Head of Research & Development effective as of March 31, 2023 and has agreed to act as a consultant to the Company effective as of April 1, 2023.
(6) Mr. Oelke was appointed Chief Science Officer in April 2022.
(7) Mr. Stover was appointed as the Company's Principal Financial and Accounting Officer in August 2023. On April 16, 2024, Mr. Stover will resign from all positions he holds at the Company.

Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table

Annual Base Salary

Base salaries of our named executive officers (other than our Chief Executive Officer) are reviewed annually and recommended to our compensation committee by our chief executive officer, and the base salary for each named executive officer is recommended by our compensation committee and approved by our board of directors. Adjustments to base salaries are based on the scope of a named executive officer's responsibilities, individual contribution, experience and performance. Decisions regarding salary increases may consider the named executive officer's current salary, equity ownership and the amounts paid to individuals in comparable positions at our company and at our peer companies provided by the Radford Group.

Annual Cash Bonus Opportunities

Under our annual bonus program for 2023, each named executive officer was eligible to be considered for an annual bonus based by our compensation committee assessment of our performance in 2022. Each named executive officer was assigned a target bonus expressed as a percentage of their base salary, which was 50% for Ms. Jones, 45% for Mr. Zeldis, 40% for Mr. Trainer and Mr. Oelke. These may be adjusted for company performance for the year based on an assessment by the compensation committee. Our board of directors approved performance bonuses for the named executive officers as reflected in the column of the Summary Compensation Table above entitled "Bonus."

On November 11, 2022, the board approved a modification to the annual bonus program for 2022, whereby each employee was guaranteed a bonus payout in the amount of 70% of their target bonus for the fiscal year 2022. The board also approved a modification and bifurcation of the annual bonus program for 2023, including a guaranteed payout in the amount of 70% of each target bonus in the first half of fiscal year 2023.

Long-Term Equity Incentives

Our equity grant program is intended to align the interests of our named executive officers with those of our stockholders and to motivate them to make important contributions to our performance.

Employment Agreements

We have entered into executive employment agreements with each of our named executive officers in connection with their employment with us, the material terms of which are described below. These executive employment agreements provide for "at will" employment, subject to certain notice and severance requirements. Each of the named executive officers was also required to enter into restrictive covenant agreements which obligate each named executive officer to refrain from disclosing any of our proprietary information received during the course of employment and to assign to us any inventions conceived or developed during the course of employment. Such restrictive covenant agreements also contain non-competition and non-solicitation protections in our favor.

Kristi Jones

We entered into an employment agreement dated as of March 8, 2022 with Ms. Jones with respect to her service as our President and Chief Executive Officer. Under the terms of the agreement, Ms. Jones will receive an annual base salary of $538,000, subject to increase by our board of directors in its discretion. Ms. Jones is also eligible to receive an annual cash bonus with a target of fifty percent (50%) of her annual salary over the time period covered by the bonus in the sole discretion of our board of directors and based on such factors that our board of directors deems appropriate. Ms. Jones is also eligible to

participate in our equity incentive plans and received on April 5, 2022, an option to acquire up to 456,000 shares of our common stock under the 2021 Plan at an exercise price equal to the Fair Market Value (as defined in the 2021 Plan) of a share of the Company's Common Stock on the grant determined in accordance with the terms of the 2021 Plan. 25% of the shares subject to the new option will vest on the first anniversary of the grant date and the remaining shares will vest in equal monthly installments over the next 36 months. Ms. Jones is also entitled to participate in our health insurance and other employee benefit plans and to receive reimbursement for business expenses and up to $15,000 of attorney's fees incurred in connection with the negotiation of her employment agreement.

Ms. Jones's employment agreement provides that in the event that (1) Ms. Jones's employment is terminated other than for cause, or (2) Ms. Jones terminates her own employment as a result of a material breach of her employment agreement by us, including any material diminution in the nature or scope of Ms. Jones's authorities, powers, functions, duties or responsibilities, following a cure period (a "Constructive Termination"), she is entitled to receive the following severance benefits: (i) a severance payment equal to 12 months of her then-current salary paid in installments; (ii) a severance payment equal to the ProRata Bonus (as defined in the employment agreement); and (iii) eligibility for at least 12 months of healthcare coverage through COBRA. If Ms. Jones's employment is terminated other than for cause or Ms. Jones terminates her own employment as a "Constructive Termination" in connection with the closing of a Change in Control (as defined in the employment agreement) or during the 12 month period following such closing, she is entitled to receive the following severance benefits: (i) a severance payment equal to 1.5 times the sum of her then-current base salary and target bonus, paid in a single lump sum; (ii) accelerated vesting and exercisability of then-unvested portion of the outstanding option awards along with any other restricted stock, stock options or other equity subject to forfeiture or rights of repurchase held by Ms. Jones; (iii) a severance payment equal to the ProRata Bonus (as defined in the employment agreement), and (iv) eligibility for 18 months of healthcare coverage through COBRA. All severance benefits are conditioned upon Ms. Jones's execution of a release of claims in our favor. If as a result of a termination of her employment Ms. Jones becomes subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, Ms. Jones is subject to a modified cutback of the payments and benefits she would otherwise receive in connection with a change in control, such that she would retain the higher of the net amount she would receive if such payments were reduced to avoid payment of the excise tax and the net amount she would receive if she received such payments in full and paid the excise tax. On any termination of Ms. Jones's employment, including due to her death or disability, she or her beneficiary is entitled to payment of all accrued and unpaid base salary, any earned but unpaid bonus, payment for all accrued but unused vacation time for the then-current annual period and all unreimbursed business expenses incurred through the date of termination. In the event of termination of her employment due to death or disability, she or her beneficiary, or if no such person is designated, her estate or personal representative, is also entitled to the ProRata Bonus (as defined in the employment agreement).

For the 2023 fiscal year, Ms. Jones was paid an annual bonus of $285,450, and was also granted options to purchase 300,000 shares of our common stock. For the 2022 fiscal year, Ms. Jones was paid an annual bonus of $148,800, and was also granted options to purchase 456,000 shares of our common stock. Ms. Jones's 2023 and 2022 options grant is subject to a four-year vesting schedule, with 25% vesting one year after the vesting commencement date and the balance vesting monthly over the remaining three years, subject to Ms. Jones's continued service through each vesting date.

John Trainer

We entered into an employment agreement dated as of January 6, 2020 with Mr. Trainer with respect to his service as our Chief Financial Officer. Under the terms of the agreement, Mr. Trainer was entitled to an initial annual base salary of $345,000, subject to increase by our board of directors. Mr. Trainer was entitled to receive options to purchase 164,719 shares of our common stock, such that his unvested stock options at that time would represent 1.2% of the fully diluted equity of the Company. Pursuant to the terms of the agreement, Mr. Trainer was also entitled to receive an annual cash bonus of up to 40% of his then-current base salary in the sole discretion of our board of directors and based on such factors that our board of directors deems appropriate. Mr. Trainer was also eligible to participate in our equity incentive plans and was entitled to participate in our health insurance and other employee benefit plans and to receive reimbursement for business expenses. Mr. Trainer was terminated through a reduction-in-force in August 2023.

Mr. Trainer's employment agreement provided that in the event that (1) Mr. Trainer's employment was terminated other than for cause, (2) Mr. Trainer terminated his own employment as a result of a material breach of his employment agreement by the Company, including any material diminution in the nature or scope of Mr. Trainer's authorities, powers, functions, duties or responsibilities, following a cure period (a "Constructive Termination"), or (3) a change of control of the Company occurs, he was entitled to receive the following severance benefits: (i) a severance payment equal to 12 months of his then-current salary and a pro-rata share of Mr. Trainer's bonus target (40% of then-current salary) paid in installments; (ii) accelerated vesting and, if applicable, exercisability of the then-unvested portion of each of his outstanding equity awards; and (iii) eligibility for at least 18 months of healthcare coverage through COBRA. These severance benefits are conditioned upon Mr. Trainer's execution of a

release of claims in favor of the Company. In the event that Mr. Trainer's employment was terminated due to his death or disability, he or his beneficiary was entitled to payment of all accrued and unpaid base salary, payment for all accrued but unused vacation time for the then-current annual period, all unreimbursed business expenses incurred through the date of termination and a pro-rata portion of his annual bonus.

For the 2023 fiscal year, Mr. Trainer was paid an annual bonus of $217,098, and was also granted options to purchase 89,100 shares of our common stock. For the 2022 fiscal year, Mr. Trainer was paid an annual bonus of $146,000, and was also granted options to purchase 78,100 shares of our common stock. The options granted to Mr. Trainer are subject to a four-year vesting schedule, with 25% vesting one year after the vesting commencement date and the balance vesting monthly over the remaining three years, subject to Mr. Trainer's continued service through each vesting date.

Jerome Zeldis

We entered into an employment agreement dated as of January 4, 2021 with Mr. Zeldis with respect to his service as our Executive Vice President, Head of Research and Development. Under the terms of the agreement, Mr. Zeldis was entitled to an initial annual base salary of $385,000, subject to increase by our board of directors. Mr. Zeldis was entitled to receive options to purchase 351,016 shares of our common stock. Pursuant to the terms of the agreement, Mr. Zeldis is also entitled to receive an annual cash bonus of up to 45% of his then-current base salary in the sole discretion of our board of directors and based on such factors that our board of directors deems appropriate. Mr. Zeldis is also eligible to participate in our equity incentive plans and is entitled to participate in our health insurance and other employee benefit plans and to receive reimbursement for business expenses.

Mr. Zeldis's employment agreement provides that in the event that (1) Mr. Zeldis's employment is terminated other than for cause, (2) Mr. Zeldis terminates his own employment as a result of a material breach of his employment agreement by the Company, including any material diminution in the nature or scope of Mr. Zeldis's authorities, powers, functions, duties or responsibilities, following a cure period (a "Constructive Termination"), or (3) a change of control of the Company occurs, he is entitled to receive the following severance benefits: (i) a severance payment equal to 12 months of his then-current salary and a pro-rata share of Mr. Zeldis's bonus target (45% of then-current salary) paid in installments; (ii) accelerated vesting and, if applicable, exercisability of the then-unvested portion of each of his outstanding equity awards; and (iii) eligibility for at least 18 months of healthcare coverage through COBRA. These severance benefits are conditioned upon Mr. Zeldis's execution of a release of claims in favor of the Company. In the event that Mr. Zeldis's employment is terminated due to his death or disability, he or his beneficiary is entitled to payment of all accrued and unpaid base salary, payment for all accrued but unused vacation time for the then-current annual period, all unreimbursed business expenses incurred through the date of termination and a pro-rata portion of his annual bonus.

For the 2023 fiscal year, Mr. Zeldis was paid an annual bonus of $158,415, and was not granted options to purchase our common stock. For the 2022 fiscal year, Mr. Zeldis was paid an annual bonus of $173,250, and was also granted options to purchase 80,100 shares of our common stock. The options granted to Mr. Zeldis are subject to a two-year vesting schedule, with 50% vesting one year after the vesting commencement date and the balance vesting monthly over the remaining one year, subject to Mr. Zeldis's continued service through each vesting date.

Mathias Oelke

We entered into an employment agreement dated as of April 5, 2022, and subsequently amended as of August 11, 2022, with Mr. Oelke with respect to his service as our Chief Scientific Officer. Under the terms of the agreement, Mr. Oelke was entitled to an initial annual base salary of $360,400, subject to increase by our board of directors. Mr. Oelke was entitled to receive options to purchase 60,000 shares of our common stock. Pursuant to the terms of the agreement, Mr. Oelke is also entitled to receive an annual cash bonus of up to 40% of his then-current base salary in the sole discretion of our board of directors and based on such factors that our board of directors deems appropriate. Mr. Oelke is also eligible to participate in our equity incentive plans and is entitled to participate in our health insurance and other employee benefit plans to receive reimbursement for business expenses, and to receive a reimbursement for a personal life insurance policy premium of up to $20,000 per year.

Mr. Oelke's employment agreement provides that in the event that (1) Mr. Oelke's employment is terminated other than for cause, (2) Mr. Oelke's terminates his own employment as a result of a material breach of his employment agreement by the Company, including any material diminution in the nature or scope of Mr. Knight's authorities, powers, functions, duties or responsibilities, following a cure period (a "Constructive Termination"), he is entitled to receive the following severance benefits: (i) a severance payment equal to 12 months of his then-current salary paid in installments; (ii) a severance payment

equal to the ProRata Bonus (as defined in the employment agreement); and (iii) eligibility for at least 18 months of healthcare coverage through COBRA. If Mr. Oelke's employment is terminated other than for cause or Mr. Oelke terminates his own employment as a "Constructive Termination" in connection with the closing of a Change in Control (as defined in the employment agreement) or during the 12 month period following such closing, he is entitled to receive, in addition to the aforementioned benefits, accelerated vesting and exercisability of then-unvested portion of the outstanding option awards along with any other restricted stock, stock options or other equity subject to forfeiture or rights of repurchase held by Mr. Oelke. These severance benefits are conditioned upon Mr. Oelke's execution of a release of claims in favor of the Company. On any termination of Mr. Oelke's employment, including due to his death or disability, him or his beneficiary is entitled to payment of all accrued and unpaid base salary, any earned but unpaid bonus, payment for all accrued but unused vacation time for the then-current annual period, and all unreimbursed business expenses incurred through the date of termination. In the event of termination of his employment due to death or disability, him or his beneficiary, or if no such person is designated, her estate or personal representative, is also entitled to the ProRata Bonus (as defined in the employment agreement).

For the 2023 fiscal year, Mr. Oelke was paid an annual bonus of $153,386, and was also granted options to purchase 81,100 shares of our common stock. For the 2022 fiscal year, Mr. Oelke was paid an annual bonus of $115,500, and was also granted options to purchase 60,000 shares of our common stock. The options granted to Mr. Oelke are subject to a four-year vesting schedule, with 25% vesting one year after the vesting commencement date and the balance vesting monthly over the remaining three years, subject to Mr. Oelke's continued service through each vesting date.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table shows grants of stock options outstanding on the last day of the year ended December 31, 2023 to each of the executive officers named in the Summary Compensation Table.

	Option Grants				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Awards: Number of Unearned Units or Other Rights That Have Not Vested	Market Value of Unearned Shares, Units or Other Rights That Have Not Vested (1)
Kristi Jones	629	—	$ 30.75	03/02/2027		
	3,526	—	$ 30.75	07/30/2028		
	148	—	$ 30.75	09/24/2028		
	979	—	$ 30.75	03/18/2029		
	752	—	$ 30.75	06/17/2029		
	2,175	—	$ 30.75	02/10/2031		
	210	982	$ 20.50	02/10/2031		
	6,460	—	$ 30.75	04/04/2032		
	1,140	10,640	$ 20.50	04/04/2032		
	—	12,000	$ 10.25	04/03/2033		
					11,868	$ 26,347
Mathias Oelke	1,895	—	$ 30.75	03/02/2027		
	631	—	$ 30.75	03/02/2027		
	4,602	—	$ 30.75	07/30/2028		
	190	—	$ 30.75	09/24/2028		
	1,277	—	$ 30.75	03/18/2029		
	514	—	$ 30.75	02/10/2031		
	—	282	$ 20.50	02/10/2031		
	850	—	$ 30.75	04/04/2032		
	150	1,400	$ 20.50	04/04/2032		
	—	3,244	$ 10.25	04/03/2033		
					5,044	$ 11,198
Timothy Stover	637	—	$ 25.75	07/05/2031		
	73	466	$ 10.25	07/05/2031		
	255	—	$ 25.75	04/04/2032		
	45	420	$ 10.25	04/04/2032		
	—	1,280	$ 10.25	04/03/2033		
					2,840	$ 6,305

(2) The market values of RSUs and restricted stock are determined by multiplying the number of shares by $2.22, the closing price of our common stock on the NASDAQ on December 29, 2023.

Potential Payments upon Termination or Change-In-Control

Executive Severance Plan

Each of the named executive officers is a participant in the Severance Plan.

Under the Severance Plan, if we terminate a participant's employment without "Cause" at any time other than during the "Change in Control Period", then the participant is eligible to receive the following benefits:

- We will pay for company contribution for continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, during the severance period.

Under the Severance Plan, if we terminate a participant's employment without "Cause" or participant resigns for "Good Reason", during the "Change in Control Period", then the participant is eligible to receive the following benefits:

- We shall reimburse the participant for all reasonable and necessary attorney's fees incurred by such participant in connection with pursuing benefits under the Severance Plan.

A participant's rights to any severance benefits under the Severance Plan are conditioned upon the participant executing and not revoking a valid separation and general release of claims agreement in a form provided by us.

The following terms have the following meanings under the Severance Plan:

- "Cause" means a participant's: (i) failure to substantially perform his/her duties and obligations to us (other than failure resulting from the participant's incapacity because of disability), including one or more acts of gross negligence or insubordination or a material breach of our policies and procedures, which failure is not cured within fifteen (15) days after a written demand for cure is received by participant from us; (ii) material breach of our code of conduct, equal opportunity and anti-harassment policies, or compliance policies (which may include, but not be limited to, a code of business conduct, an anti-bribery policy, a competition policy, and a policy on healthcare business ethics); (iii) commission, indictment, conviction, or entry of a plea of guilty or nolo contendere to, a felony or any other crime involving fraud, dishonesty, theft, breach of trust or moral turpitude; (iv) engagement in misconduct which results in, or could reasonably be expected to result in, material injury to our financial condition, reputation, or ability to do business; (v) material breach of a written agreement with us, including any confidentiality, invention assignment, non-competition, non-solicitation or non-disparagement agreement; (vi) violation of state or federal securities laws or regulations; or (vii) willful failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by us to cooperate, willful destruction or failure to preserve documents or other materials relevant to such investigation, or willful inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.
- "Good Reason" shall mean the occurrence of any of the following without participant's prior consent: (i) a material decrease in participant's base salary or bonus opportunity; (ii) a material diminution in the aggregate employee benefits and material perquisites provided to participant; (iii) a material diminution in participant's title, reporting relationship, duties or responsibilities; (iv) a relocation of participant's primary office by more than thirty-five (35) miles from participant's then-current location; and (v) the failure by any successor to us or any acquiring corporation to explicitly assume the Severance Plan and our obligations thereunder and maintain the Severance Plan in effect for a period of at least twenty-four (24) months.
- "Change in Control" is defined as a transaction or a series of related transactions in which: (i) all or substantially all of our assets are transferred to any "person" or "group" (as such terms are defined in the Exchange Act); (ii) any person or group, other than person or group who prior to such acquisition is a "beneficial owner" (as defined under the Exchange Act), directly or indirectly, of any of our equity, becomes the "beneficial owner", directly or indirectly, of our outstanding equity representing more than 50% of the total voting power of our then-outstanding equity; (iii) we undergo a merger, reorganization or other consolidation in which the holders of our outstanding equity immediately prior to such merger, reorganization or consolidation directly or indirectly own less than 50% of the surviving entity's voting power immediately after the transaction; or (iv) if within any rolling twelve month period, the persons who were our directors at the beginning of such twelve month period, or the incumbent directors, cease to constitute at least a majority of such board of directors; provided that any director who was not a director at the beginning of such twelve (12) month period will be deemed to be an incumbent director if that director was elected to the board of directors by, or on the recommendation of or with the approval of, a majority of the directors who then qualified as incumbent directors. Any of (i) through (iv) above may constitute a Change in Control, provided that the Change in Control meets all of the requirements of a "change in the ownership of a corporation," a "change in the effective ownership of a corporation," or "a change in the ownership of a substantial portion of the corporation's assets," each within the meaning of Treasury Regulation §1.409A-3(i)(5).
- "Change in Control Period" means: (i) the twenty-four (24) month period beginning on the date of a Change in Control; (ii) any such time prior to a Change in Control where the successor or acquiring entity in the Change in Control requests for the termination of a participant's employment without Cause; or (iii) any such time prior to a Change in Control where we terminate a participant's employment without Cause in connection with or in anticipation of a Change in Control.

Director Compensation

The following table sets forth the total compensation paid during the fiscal year ended December 31, 2023 to each of our directors, other than Ms. Jones who did not receive compensation for her service as a director.

Name	Total
Sol J. Barer, Ph.D.	$ 102,000
Alan S. Roemer, M.B.A., M.P.H.	62,500
Tim Bertram, Ph.D.	57,500
Paul D'Angio, R.P.H., M.S.J.	62,500
Zhengbin (Bing) Yao, Ph.D.	64,000
Grant Verstandig	44,000
Leena Gandhi	26,154

The following table shows the aggregate grant date fair value for option awards granted during the fiscal year ended December 31, 2023, computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 3 to our financial statements for the fiscal year ended December 31, 2023 included elsewhere in this Annual Report.

Name	Grant Date Fair Value	Number of Stock Options Held at Fiscal Year-End
Sol J. Barer, Ph.D.	$ 9,888	1,799
Alan S. Roemer, M.B.A., M.P.H.	9,888	1,799
Tim Bertram, Ph.D.	9,888	1,799
Paul D'Angio, R.P.H., M.S.J.	9,888	1,799
Zhengbin (Bing) Yao, Ph.D.	9,888	1,799
Grant Verstandig	9,888	1,799
Leena Gandhi	9,888	1,799

Non-Employee Director Compensation Policy

We have adopted a policy with respect to the compensation payable to our non- employee directors. Under this policy, each non-employee director will be eligible to receive compensation for his or her service consisting of annual cash retainers and equity awards. Our non-employee directors will receive the following annual retainers for their service:

Position	Retainer
Board Chairperson	$ 65,000
Audit Committee Chairperson	22,500
Compensation Committee Chairperson	15,000
Transaction Committee Chairperson	15,000
Technical Operations Committee Chairperson	15,000
Science and Technical Committee Chairperson	15,000
Nominating and Governance Committee Chairperson	12,000
Board Member	35,000
Audit Committee Member	7,500
Compensation Committee Member	5,000
Transaction Committee Member	5,000
Technical Operations Committee Member	5,000
Science and Technical Committee Member	5,000
Nominating and Governance Committee Member	4,000

Equity awards for non-employee directors will consist of consist of an annual equity award consisting of options to purchase 1,799 shares of common stock annual, vesting 12 months after the grant date.

Directors may be reimbursed for travel, food, lodging and other expenses directly related to their service as directors. Directors are also entitled to the protection provided by their indemnification agreements and the indemnification provisions in our certificate of incorporation and bylaws.

Equity Compensation Plan and Other Benefit Plans

Our 2017 Equity Incentive Plan, or the 2017 Plan, was approved by our board of directors and stockholders in January 2017, and was subsequently amended in April 2017. The 2017 Plan provides for the issuance of up to 26,434 shares of our common stock. The 2017 Plan allows us to make grants of stock options, restricted stock, restricted stock units and stock appreciation rights to our employees, directors and consultants. As of January 31, 2021, under the 2017 Plan, options to purchase 20,384 shares of our common stock were outstanding, 5,938 shares of our common stock had been issued and were outstanding pursuant to the exercise of options granted under the 2017 Plan, and 107 shares of our common stock were available for future awards under the 2017 Plan, which shares are no longer available for issuance.

Our 2018 Equity Incentive Plan, or the 2018 Plan, was approved by our board of directors in June 2018 and our stockholders in July 2018, and was subsequently amended in July 2018. The 2018 Plan and 2017 Plan are collectively referred to as the “Equity Plans.” The 2018 Plan provides for the issuance of up to 72,279 shares of our common stock. The 2018 Plan allows us to make grants of stock options, restricted stock, restricted stock units and stock appreciation rights to our employees, directors and consultants. As of January 31, 2021, under the 2018 Plan, options to purchase 61,723 shares of our common stock were outstanding, 85 shares of our common stock had been issued and were outstanding pursuant to the exercise of options granted under the 2018 Plan, and 10,555 shares of our common stock were available for future awards under the 2018 Plan, which shares are no longer available for issuance.

Our 2021 Equity Incentive Plan, or the 2021 Plan, was approved by our board of directors in January 2021 and our stockholders in February 2021. The 2021 Plan, the 2018 Plan and the 2017 Plan are collectively referred to as the “Equity Plans.” The 2021 Plan provides for the issuance of up to 110,289 shares of our common stock, which includes 10,662 shares of common stock previously reserved for issuance pursuant to future awards under our 2017 Plan and our 2018 Plan, which shares will cease to be available for issuance under the 2017 Plan and the 2018 Plan. In addition, the 2021 Plan contains an “evergreen” provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the 2021 Plan on the first day of each calendar year beginning in calendar year 2022. The annual increase in the number of shares shall be equal to the lower of (i) 5.0% of the number of shares of our common stock outstanding on the date of the

applicable increase or (ii) a lesser amount determined by our board of directors. The 2021 Plan allows us to make grants of stock options, restricted stock, restricted stock units and stock appreciation rights to our employees, directors and consultants.

Under the Equity Plans, in the event there is a specified type of change in our capital structure, such as a recapitalization or stock split, appropriate adjustments will be made to (i) the class(es) and maximum number of securities subject to the Equity Plans, (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of incentive stock options, and (iii) the class(es) and number of securities and price per share of stock subject to outstanding stock awards under the Equity Plans.

The Equity Plans also provide that in the event of a corporate transaction (as defined in the Equity Plans and described below), and except as otherwise stated in a stock option or other award agreement, our board of directors will take one or more of the following actions with respect to outstanding stock awards: (i) arrange for the surviving corporation or acquiring corporation to assume or substitute for the outstanding stock awards; (ii) accelerate the vesting of outstanding stock awards, with such awards terminating if not exercised prior to the effective time of the corporate transaction, (iii) terminate or cancel outstanding stock awards to the extent not vested or exercised prior to the effective time of the corporate transaction; or (iv) make a payment equal to the excess of the value the holder would receive upon exercise of the award over the exercise price payable by the holder.

Under the Equity Plans, a corporate transaction is generally the consummation of: (i) a sale or other disposition of all or substantially all of the assets of the Company and its subsidiaries; (ii) a sale or other disposition of at least 90% of the securities of the Company; (iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of our common stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 1, 2024, for (a) the executive officers named in the Summary Compensation Table on page 127 of this Annual Report on Form 10K, (b) each of our directors and director nominees, (c) all of our current directors and executive officers as a group and (d) each stockholder known by us to own beneficially more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of March 1, 2024, pursuant to the exercise of options to be outstanding for the purpose of computing the percentage ownership of such individual or group, but those shares are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on

information provided to us by these stockholders. Percentage of ownership is based on 1,371,051 shares of common stock outstanding on March 1, 2024.

	Shares Beneficially Owned	
Name and Address**	**Number**	**Percent**
More than 5% stockholders:		
B&S NexImmune Holdco LLC and Joshua Barer (1)	75,383	5.5 %
Directors and executive officers:		
Sol J. Barer, Ph.D. (2)	98,179	7.1 %
Alan S. Roemer, M.B.A., M.P.H. (3)	3,928	*
Tim Bertram, Ph.D. (4)	7,406	*
Paul D'Angio, R.P.H., M.S.J. (5)	5,392	*
Zhengbin (Bing) Yao, Ph.D. (6)	4,279	*
Grant Verstandig (7)	48,249	3.5 %
Leena Gandhi, M.D., Ph.D. (8)	2,068	*
Kristi Jones (9)	23,747	1.7 %
Mathias Oelke, Ph.D. (10)	11,554	*
Timothy Stover (11)	1,488	*
All directors and current executive officers as a group (10) persons	206,290	14.9 %

*** Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.**

**** Unless otherwise indicated, the address for each beneficial owner listed is c/o NexImmune, Inc., 9119 Gaither Road, Gaithersburg, MD 20877.**

(1) Consists of (a) 61,520 shares of our common stock held by B&S NexImmune Holdco, LLC, and (b) 13,863 shares of our common stock Joshua Barer. Joshua Barer is the sole manager of B&S NexImmune Holdco LLC and has sole voting and dispositive control over the shares held by B&S NexImmune Holdco LLC. Mr. Barer may be considered the beneficial owner of the shares held by B&S NexImmune Holdco LLC and disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Sol J. Barer, Ph.D., one of our directors and the father of Joshua Barer, is a member of Barer & Son Capital, LLC, which is a member of B&S NexImmune Holdco LLC, but Sol J. Barer, Ph.D. does not have voting or dispositive control over the shares held by B&S NexImmune Holdco LLC. The principal business address of B&S NexImmune Holdco LLC and Mr. Barer is 2 Barer Lane, Mendham, New Jersey 07945.

(2) Consists of 88,712 shares of common stock and 9,467 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Dr. Barer. Does not include the securities held by B&S NexImmune Holdco LLC discussed in footnote 1, as Dr. Barer has no voting or dispositive control over such securities.

(3) Consists of 3,928 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Mr. Roemer. Does not include the securities held by the Alan S. Roemer 2015 Family Trust, as Mr. Roemer has no voting or dispositive control over such securities.

(4) Consists of 3,127 shares of common stock and 4,279 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Dr. Bertram.

(5) Consists of 1,113 shares of common stock and 4,279 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Mr. D'Angio.

(6) Consists of 505 shares of common stock and 3,774 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Dr. Yao.

(7) Consists of 44,219 shares of common stock and 4,030 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Mr. Verstandig.

(8) Consists of 2,068 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Ms. Gandhi.

(9) Consists of 2,923 shares of common stock and 20,824 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Ms. Jones. Does not include 11,868 shares underlying restricted stock units that are unvested or will not vest within 60 days of March 1, 2024 held by Ms. Jones.

(10) Consists of 316 shares of common stock and 11,238 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Mr. Oelke. Does not include 5,044 shares underlying restricted stock units that are unvested or will not vest within 60 days of March 1, 2024 held by Mr. Oelke.

(11) Consists of 1,488 shares of common stock underlying options that are exercisable as of March 1, 2024 or will become exercisable within 60 days after such date held by Mr. Stover. Does not include 2,840 shares underlying restricted stock units that are unvested or will not vest within 60 days of March 1, 2024 held by Mr. Stover.

Securities Authorized for Issuance under Equity Incentive Plans

Equity Compensation Plan Information

The following table provides certain aggregate information with respect to all of the Company's equity compensation plans in effect as of March 1, 2024.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options		(b) Weighted-average exercise price of outstanding options	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))	
Equity compensation plans approved by security holders(1)	10,610	(1)	$ 48.83	—	(2)
Equity compensation plans approved by security holders(3)	25,363	(3)	$ 41.22	—	(4)
Equity compensation plans approved by Security holders(4)	109,092	(5)	$ 23.13	152,533	(6)
Equity compensation plans not approved by security holders	—		—	—	
Total	145,065		$ 29.30	152,533	

(1) Consist of options to purchase 10,610 shares of our common stock outstanding under 2017 Equity Incentive Plan as of March 1, 2024.
(2) No additional stock awards will be granted under the 2017 Plan and the shares remaining available for the grant of future stock awards under the 2017 Plan, are available for the grant of stock awards under the 2021 Plan.
(3) Consist of options to purchase 25,363 shares of our common stock outstanding under the 2018 Equity Incentive Plan as of March 1, 2024.
(4) No additional stock awards will be granted under the 2018 Plan and the shares remaining available for the grant of future stock awards under the 2018 Plan, are available for the grant of stock awards under the 2021 Plan.
(5) Consist of options to purchase 82,632 shares of our common stock outstanding and the right to receive 26,460 RSUs of common stock under the 2021 Equity Incentive plan as of March 1, 2024.
(6) Represents shares of common stock reserved for issuance upon the exercise of options granted or RSUs awarded under the 2021 Plan as of March 1, 2024.

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

Our Audit committee reviews and approves in advance all related-party transactions. In addition to the director and executive officer compensation arrangements discussed above in "Executive Officer and Director Compensation," during the fiscal year ended December 31, 2023, we have not engaged any transactions in which the amount involved exceeded $120,000 and in which any director, executive officer or holder of more than 5% of our voting securities, whom we refer to as our principal stockholders, or affiliates or immediately family members of our directors, executive officers and principal stockholders, had or will have a material interest.

Agreements with Stockholders

Amended and Restated Investors' Rights Agreement

We entered into a Second Amended and Restated Investors' Rights Agreement, dated as of November 27, 2019, or the Investors' Rights Agreement, with certain holders of our capital stock. With the completion of the IPO, the holders of 10,144,041 shares of our common stock, including shares issued upon the automatic conversion of our convertible preferred stock, or their permitted transferees, which we refer to as our registrable securities, are entitled to rights with respect to the registration of these securities under the Securities Act. These shares also may be sold under Rule 144 under the Securities Act, depending on their holding period and subject to restrictions in the case of shares held by persons deemed to be our affiliates.

Under the Investors' Rights Agreement, holders of registrable shares can demand that we file a registration statement or request that their shares be included on a registration statement that we are otherwise filing, in either case, registering the resale of their shares of common stock. These registration rights are subject to conditions and limitations, including the right, in certain circumstances, of the underwriters of an offering to limit the number of shares included in such registration and our right, in certain circumstances, not to effect a registration upon demand of the holders of registrable shares within 90 days

following the effective date of any registration statement that we file covering a firm commitment underwritten public offering in which the holders of registrable shares were entitled to join and in which we effectively registered all registrable shares that were requested to be registered.

Demand Registration Rights

Beginning on August 11, 2021, the holders of at least 25% of registrable securities then outstanding under the Investors' Rights Agreement may require us to file a registration statement under the Securities Act on a Form S-1 at our expense, subject to certain exceptions, with respect to at least 40% of the registrable securities then outstanding, and we are required to effect the registration as soon as practicable, and in any event within 60 days. Any time after we are eligible to use a registration statement on Form S-3, the holders of at least 20% of our registrable securities under the Investors' Rights Agreement may require us to file a registration statement on Form S-3 at our expense, subject to certain exceptions, with respect to the resale of their registrable shares, and we are required to effect the registration as soon as practicable, and in any event within 45 days.

Piggyback Registration Rights

If we propose to file a registration statement under the Securities Act for the purposes of a public offering of our securities including, but not limited to, registration statements relating to a secondary offering of our securities but excluding (i) a registration statement relating to the sale of securities to employees pursuant to a stock option, stock purchase, or similar plan; (ii) with respect to any corporate reorganization or transaction under Rule 145 of the Securities Act; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registrable securities; or (iv) a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered. The underwriters of the offering will have the right to limit the number of shares to be included in such registration.

Expenses of Registration

We will pay all registration expenses, other than underwriting discounts and commissions, related to any demand or piggyback registration. The amended and restated investors' rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders, in the event of misstatements or omissions in the registration statement attributable to us except in the event of fraud, and they are obligated to indemnify us for misstatements or omissions attributable to them.

Expiration of Registration Rights

The registration rights will terminate upon the earliest to occur of the closing of certain liquidation events, such time when all of the holder's registrable securities may be sold without limitation (and without the requirement for us to be in compliance with the current public information requirement) under Rule 144 of the Securities Act and the fifth anniversary of the closing date of our initial public offering.

Indemnification Agreements with Officers and Directors and Directors' and Officers' Liability Insurance

In connection with our initial public offering, we entered into, and intend to continue to enter into, indemnification agreements with each of our executive officers and directors. The indemnification agreements, our third amended and restated certificate of incorporation and our amended and restated bylaws became effective upon completion of our initial public offering and require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our amended and restated bylaws require us to advance expenses incurred by our directors and officers. We also maintain a general liability insurance policy, which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Policies and Procedures for Related Party Transactions

In connection with our initial public offering, we adopted a written policy that requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons, as defined in Item 404 of Regulation S-K, or their affiliates, in which the amount involved is equal to or greater than $120,000, be approved in advance by our Audit committee. Any request for such a transaction must first be presented to our Audit committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit committee will consider the relevant facts and circumstances available and deemed relevant to the Audit committee, including, but not limited to, the extent of the related party's interest in

the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

Item 14. Principal Accounting Fees and Services.

The following table presents fees for professional audit services rendered by Ernst & Young LLP, our independent registered public accounting firm, for the years ended December 31, 2023 and 2022.

	2023	2022
Audit fees (1)	$ 715,000	$ 800,383
All other fees	—	2,000
Total	$ 715,000	$ 802,383

(1) Audit fees relate to professional services rendered in connection with the audit of NexImmune's annual financial statements, quarterly review of financial statements, and audit services provided in connection with other statutory and regulatory filings, including fees related to our registration statement filings and consents, comfort letters. There were no audit-related, tax or other fees incurred for the years ended December 31, 2023 and 2022.

All fees described above were pre-approved by our Audit committee. We have furnished the foregoing disclosure to Ernst & Young LLP.

Policy on Audit committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit committee for approval. Management and our independent registered public accounting firm will each confirm to our Audit Committee that each non-audit service is permissible under all applicable legal requirements.

1. ***Audit*** services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.
2. ***Audit-Related*** services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.
3. ***Tax*** services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.
4. ***Other Fees*** are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit committee pre-approves these services by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit committee at its next scheduled meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The financial statements filed as part of this Annual Report on Form 10-K are listed in the Index to Financial Statements. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto. The Exhibits are listed in Item 15(b) below.

(b) Exhibit Index.

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
3.1	Form of Sixth Amended and Restated Certificate of Incorporation.		8-K	02/18/21	001-40045
3.2	Certificate of Amendment of Six Amended and Restated Certificate of Incorporation		8-K	10/18/23	001-40045
3.3	Restated Bylaws of NexImmune, Inc.		8-K	02/18/21	001-40045
4.1	Form of Common Stock Certificate.		S-1/A	02/08/21	333-252220
4.2	Second Amended and Restated Investors' Rights Agreement, by and between the Company and the stockholders of the Company listed therein, dated November 27, 2019.		S-1/A	02/08/21	333-252220
4.3	Form of Convertible Promissory Note, as amended.		S-1/A	02/08/21	333-252220
4.4	Description of Securities.		10-K	03/31/21	001-40045
10.1	Form of Indemnification Agreement.		S-1/A	02/08/21	333-252220
10.2.1+	2017 Equity Incentive Plan, as amended.		S-1/A	02/08/21	333-252220
10.2.2+	Form of Stock Option Agreement under the 2017 Equity Incentive Plan, as amended.		S-1/A	02/08/21	333-252220
10.3.1+	2018 Equity Incentive Plan, as amended.		S-1/A	02/08/21	333-252220
10.3.2+	Form of Stock Option Agreement under the 2018 Equity Incentive Plan, as amended.		S-1/A	02/08/21	333-252220
10.4.1+	2021 Equity Incentive Plan.		S-1/A	02/08/21	333-252220
10.4.2+	Form of Stock Option Agreement under the 2021 Equity Incentive Plan.		S-1/A	02/08/21	333-252220
10.5+	Employment Agreement, by and between the Company and Scott Carmer, dated February 3, 2021.		S-1/A	02/08/21	333-252220
10.6+	Employment Agreement, by and between the Company and John Trainer, M.B.A., dated January 6, 2020.		S-1/A	02/08/21	333-252220
10.7.1+	Employment Agreement, by and between the Company and Jerome Zeldis, M.D., Ph.D., dated January 4, 2021.		S-1/A	02/08/21	333-252220
10.7.2+#	Consultation Agreement, by and between the Company and Jerome Zeldis, M.D., Ph.D., dated March 23, 2023		10-K	03/28/23	001-40045

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
10.8.1+	Employment Agreement, by and between the Company and Kristi Jones, dated February 27, 2017.		S-1/A	02/08/21	333-252220
10.8.2+	Employment Agreement, by and between the Company and Kristi Jones, dated March 8, 2022.		10-K	03/09/22	001-40045
10.9+	Employment Agreement, by and between the Company and Robert Knight, M.D., dated January 6, 2021.		10-Q	05/17/21	001-40045
10.10+	Non-Employee Director Compensation Policy.		S-1/A	02/08/21	333-252220
10.11#	Amended and Restated Exclusive License Agreement, by and between the Johns Hopkins University and the Company, dated June 21, 2011.		S-1	01/19/21	333-252220
10.12	Lease Agreement, by and between the Company and W. M. Rickman Construction Co., LLC, dated June 30, 2017.		S-1	01/19/21	333-252220
10.13	Sublease Agreement, by and between the Company and Modavar Pharmaceuticals LLC, dated December 11, 2017.		S-1	01/19/21	333-252220
10.14	Joint Research Agreement, by and between Zephyr AI, Inc. and NexImmune, Inc., dated March 16, 2022		10-Q	05/12/22	001-40045
23.1	Consent of Ernst & Young LLP	X			
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
97.1+	NexImmune, Inc. Clawback Policy	X			
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
101.PRE	Inline XBRL Taxonomy Extension Presentation	X			
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document contained in Exhibit 101	X			

Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

+ Denotes management compensation plan or contract.

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

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

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

NEXIMMUNE, INC.

Date: April 16, 2024

By: /s/ Kristi Jones
Kristi Jones, R.P.H.
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Kristi Jones Kristi Jones, R.P.H.	President, Chief Executive Officer and Director *(principal executive officer)*	April 16, 2024
/s/ Timothy Stover Timothy Stover	Vice President, Corporate Controller (principal accounting officer and principal financial officer)	April 16, 2024
/s/ Sol J. Barer Sol J. Barer, Ph.D.	Chairperson of the Board of Directors	April 16, 2024
/s/ Alan S. Roemer Alan S. Roemer, M.B.A., M.P.H.	Director	April 16, 2024
/s/ Tim Bertram Tim Bertram, Ph.D.	Director	April 16, 2024
/s/ Paul D'Angio Paul D'Angio, R.P.H., M.S.J.	Director	April 16, 2024
/s/ Zhengbin (Bing) Yao Zhengbin (Bing) Yao, Ph.D.	Director	April 16, 2024
/s/ Grant Verstandig Grant Verstandig	Director	April 16, 2024
/s/ Leena Gandhi Leena Gandhi, M.D., Ph.D.	Director	April 16, 2024

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of NexImmune, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NexImmune, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring operating losses, has negative cash flows from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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.

/s/ Ernst & Young LLP

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

Tysons, Virginia
April 16, 2024

NEXIMMUNE, INC.

BALANCE SHEETS

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,202,452	$ 34,642,340
Restricted cash	20,000	55,000
Assets held for sale	1,444,043	—
Prepaid expenses and other current assets	734,464	2,671,411
Total current assets	5,400,959	37,368,751
Property and equipment, net	1,352,901	4,459,071
Operating lease right-of-use assets, net	46,716	967,032
Other non-current assets	1,793,373	264,970
Total assets	$ 8,593,949	$ 43,059,824
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,336,318	$ 2,377,374
Accrued expenses and other current liabilities	3,679,105	7,357,153
Operating lease liabilities, current	68,809	599,047
Total current liabilities	5,084,232	10,333,574
Operating lease liabilities, non-current	—	425,766
Total liabilities	5,084,232	10,759,340
Commitments and contingencies		
Stockholders' equity		
Common Stock, $0.0001 par value, 250,000,000 shares authorized as of December 31, 2023 and 2022, 1,066,320 and 1,043,138 issued and outstanding as of December 31, 2023 and 2022	2,646	2,608
Additional paid-in-capital	226,101,118	222,547,530
Accumulated deficit	(222,594,047)	(190,249,654)
Total stockholders' equity	3,509,717	32,300,484
Total liabilities and stockholders' equity	$ 8,593,949	$ 43,059,824

On October 18, 2023, the Company effected a one-for-twenty five (1-for-25) reverse stock split of its common stock. The total authorized number of shares were not reduced. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

The accompanying notes are an integral part of these financial statements

NEXIMMUNE, INC.
STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 19,282,230	$ 47,148,450
General and administrative	13,000,624	15,934,439
Loss on assets held for sale	690,768	—
Total operating expenses	32,973,622	63,082,889
Loss from operations	(32,973,622)	(63,082,889)
Other income (expense), net:		
Interest income	698,395	664,372
Other expense	(69,166)	(87,682)
Total other income, net	629,229	576,690
Net loss	(32,344,393)	(62,506,199)
Net loss available to common stockholders'	$ (32,344,393)	$ (62,506,199)
Basic and diluted net loss available to common stockholders per common share	$ (30.82)	$ (64.95)
Basic and diluted weighted-average number of common shares outstanding	1,049,468	962,364

On October 18, 2023, the Company effected a one-for-twenty five (1-for-25) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,	
	2023	2022
Net loss	$ (32,344,393)	$ (62,506,199)
Other comprehensive loss:		
Unrealized gain loss on available-for-sale marketable securities, net of tax	—	(3,012)
Comprehensive loss	$ (32,344,393)	$ (62,509,211)

On October 18, 2023, the Company effected a one-for-twenty five (1-for-25) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

The accompanying notes are an integral part of these financial statements

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Years Ended December 31, 2023 and 2022

	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/ (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2023	1,043,138	$ 2,608	$ 222,547,530	$ (190,249,654)	$ —	$ 32,300,484
Settlement of restricted stock units, net	23,258	38	(38)	—	—	—
Fractional shares adjustment due to reverse split	(76)	—	—	—	—	—
Stock-based compensation	—	—	3,553,626	—	—	3,553,626
Unrealized gain on marketable available-for-sale securities	—	—	—	—	—	—
Net loss	—	—	—	(32,344,393)	—	(32,344,393)
Balance at December 31, 2023	1,066,320	$ 2,646	$ 226,101,118	$ (222,594,047)	$ —	$ 3,509,717

On October 18, 2023, the Company effected a one-for-twenty five (1-for-25) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

The accompanying notes are an integral part of these financial statements

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Years Ended December 31, 2023 and 2022 (Continued)

	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/ (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2022	913,156	$ 2,283	$ 211,498,827	$ (127,743,455)	$ 3,012	$ 83,760,667
Issuance of common stock from "at-the-market" offering facility, net of transaction costs	127,396	319	5,145,090	—	—	5,145,409
Exercise of stock options	516	1	33,254	—	—	33,255
Cashless exercise of options for common stock	2,070	5	(5)	—	—	—
Stock-based compensation	—	—	5,870,364	—	—	5,870,364
Unrealized loss on marketable available-for-sale securities	—	—	—	—	(3,012)	(3,012)
Net loss	—	—	—	(62,506,199)	—	(62,506,199)
Balance at December 31, 2022	1,043,138	$ 2,608	$ 222,547,530	$ (190,249,654)	$ —	$ 32,300,484

On October 18, 2023, the Company effected a one-for-twenty five (1-for-25) reverse stock split of its common stock. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

The accompanying notes are an integral part of these financial statements

NEXIMMUNE, INC.
STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (32,344,393)	$ (62,506,199)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,024,973	994,792
Accretion income on available-for-sale marketable securities, net	—	(1,131)
Loss on assets held for sale	690,768	—
Gain or loss on assets disposal	(14,492)	21,264
Stock-based compensation	3,553,626	5,870,364
Non-cash lease expense	537,406	500,553
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,946,949	1,723,506
Other non-current assets	(1,528,403)	59,129
Accounts payable	(1,041,058)	1,387,057
Accrued expenses and other	(3,682,677)	1,258,098
Operating lease liabilities	(573,095)	(498,353)
Net cash used in operating activities	(31,430,396)	(51,190,920)
Cash flows from investing activities		
Purchase of property and equipment	(48,720)	(1,255,116)
Proceeds from disposal of equipment	4,228	80,800
Purchases of available-for-sale marketable securities	—	(21,509,940)
Proceeds from maturities of available-for-sale marketable securities	—	71,500,000
Proceeds from redemption of available-for-sale marketable securities	—	1,500,000
Net cash (used in) provided by investing activities	(44,492)	50,315,744
Cash flows from financing activities		
Proceeds from "at-the-market" offering facility, net of transaction costs	—	5,145,409
Proceeds from the exercise of stock options	—	33,255
Net cash provided by financing activities	—	5,178,664
Net increase in cash, cash equivalents and restricted cash	(31,474,888)	4,303,488
Net cash, cash equivalents and restricted cash at beginning of period	34,697,340	30,393,852
Net cash, cash equivalents and restricted cash at end of period	$ 3,222,452	$ 34,697,340
Supplemental disclosure of noncash investing and financing activities:		
Leased assets exchanged for operating lease liabilities	$ 382,910	$ —
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ 5,370

The accompanying notes are an integral part of these financial statements

NexImmune, Inc.
NOTES TO FINANCIAL STATEMENTS
For the years ended December 31, 2023 and 2022

1. Description of the Business

NexImmune, Inc. (the "Company" or "NexImmune"), a Delaware corporation headquartered in Gaithersburg, Maryland, was incorporated on June 7, 2011. The Company is an emerging biopharmaceutical company advancing a new generation of immunotherapies based on its proprietary Artificial Immune Modulation (AIM) technology. The AIM nanotechnology platform, originally developed at Johns Hopkins University, is the foundation for an innovative approach to immunotherapy in which the body's own immune system is stimulated to orchestrate a targeted T cell response against a disease. Central to the AIM technology are artificial AIM nanoparticles, which act as synthetic dendritic cells. These AIM nanoparticles can be programmed to present specific antigens to specific T cells orchestrating a highly targeted immune response. These AIM nanoparticles can be rapidly engineered to elicit an immune attack that can be directed toward any foreign substance or cell type in a patient's body. The Company's first two products, both for the treatment of different types of cancer, entered clinical trials in 2020. Following a strategic review of the Company's corporate strategy, including with respect to its adoptive cell therapy programs, the Company paused investments in its cell therapy studies, NEXI-001, NEXI-002, and NEXI-003 which is designed to reduce costs and reallocate resources towards our AIM INJ preclinical development programs. As part of this strategy, the Company will focus on developing AIM INJ nanoparticle constructs and modalities for potential clinical evaluation in oncology and autoimmune disorders. The Company continues to explore several external opportunities to continue to advance these programs. As a result, the Company will focus its existing resources on its injectable platform in oncology and autoimmune diseases.

Going Concern

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, Presentation of Financial Statements - Going Concern ("ASC 205-40"), requires management to assess the Company's ability to continue as a going concern for one year after the date the financial statements are issued. Under ASC 205-40, management has the responsibility to evaluate whether conditions and/or events raise substantial doubt about the Company's ability to meet future financial obligations as they become due within one year after the date that the financial statements are issued. As required by this standard, management's evaluation shall initially not take into consideration the potential mitigating effects of management's plans that have not been fully implemented as of the date the financial statements are issued.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Since its inception, the Company has incurred recurring operating losses and negative cash flows from operations. The financial statements do not include any adjustments relating to the realization of the carrying value of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

As of December 31, 2023, the Company had an accumulated deficit of $222.6 million and negative cash flows from operating activities for the year ended December 31, 2023. The Company has no outstanding debt, $3.2 million in cash and cash equivalents as of December 31, 2023 and no other access to significant capital. The Company expects its negative cash flows from operating activities to exceed its currently available liquidity and thus has determined that its losses and negative cash flows from operations and uncertainty in obtaining additional liquidity to meet its obligations and sustain our operations raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the issuance date of these financial statements.

As the Company's research and development activities mature and develop over the next year, the Company will require substantial funds to continue such activities. As discussed below, as a result of the financing consummated in February 2024, the Company determined to postpone its previously scheduled special meeting of stockholders for the purpose of approving the liquidation and dissolution of the Company. If the Company is unable to raise additional capital or otherwise achieve other alternatives to maximize the value of the business and its assets, the Company would expect to call a new special meeting of stockholders to seek approval of the liquidation and dissolution of the Company.

There are inherent uncertainties associated with fundraising activities which are not within the Company's control. There are no assurances that such additional funding will be obtained, or that any funding that may be obtained would be sufficient for the Company to meet its obligations as they become due within one year, or that the Company will succeed in its future operations. If the Company cannot successfully raise additional capital, its liquidity, financial condition and business prospects

1. Description of the Business (continued)

will be materially and adversely affected. The Company is continually looking into further capital planning and the evaluation of strategic alternatives. There is substantial doubt about the Company's ability to continue as a going concern.

Reverse Stock Split

On October 18, 2023, the Company effected a one-for-twenty-five (1-for-25) reverse stock split of its common stock (the "Reverse Stock Split"). The total authorized number of shares were not reduced. The Reverse Stock Split, which was approved by stockholders at an annual stockholder meeting on October 17, 2023, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on October 18, 2023. The Reverse Stock Split was effective on October 18, 2023. All references to common stock, warrants to purchase common stock, options to purchase common stock, share data, per share data and related information contained in the financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Approval of Plan of Dissolution and Postponement of Special Meeting

On November 2, 2023, the Board of Directors of the Company, or the Board, unanimously approved the liquidation and wind up of the Company through a dissolution pursuant to a plan of liquidation and dissolution, or the Plan of Liquidation and Dissolution, subject to stockholder approval, while continuing to pursue alternatives intended to maximize the value of the business and its assets.

On February 2, 2024, the Company entered into a securities purchase agreement, or the "Purchase Agreement" with a single healthcare focused institutional investor, or the "Investor", pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market, or the "Registered Offering", (i) an aggregate of 117,000 shares, or the "Shares" of common stock, par value $0.0001, of the Company, or the "Common Stock", at an offering price of $12.05 per share, and (ii) pre-funded warrants the "Pre-Funded Warrants" exercisable for up to 187,731 shares of Common Stock the "Pre-Funded Warrant Shares", at an offering price of $12.049 per Pre-Funded Warrant, for aggregate gross proceeds from the offerings of approximately $3.7 million before deducting the placement agent fee and related offering expenses. The offerings closed February 6, 2024 and all Pre-Funded Warrants were exercised prior to March 1, 2024.

As a result of the financing described above, the Company has determined to postpone its special meeting of stockholders for the purpose of approving the liquidation and dissolution of the Company and the Plan of Liquidation, which was previously scheduled to reconvene on Wednesday, February 7, 2024.

2. Basis of Presentation and Liquidity

Basis of Presentation

The accompanying financial statements were prepared based on the accrual method of accounting in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Updates ("ASU") of the FASB.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, the Company evaluates its estimates, including those related to the recoverability of long-lived assets, stock-based compensation, the valuation of financial instruments, and the valuation of deferred tax assets and liabilities. The Company's estimates are based on historical experience and on various other assumptions that the Company believes to be

3. Summary of Significant Accounting Policies (continued)

reasonable under the circumstances. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Concentrations of credit risk

Financial instruments which potentially subject the Company to credit risk consist principally of cash and marketable debt securities. All cash is held in United States financial institutions that are federally insured. At times, the Company may maintain cash balances in excess of the federally insured amount. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk. The Company's investments in marketable debt securities have been issued by corporate entities and government-sponsored enterprises with high credit ratings. The Company mitigates investment risks by investing in highly-rated securities with relatively short maturities that the Company believes do not subject it to undue investment or credit risk. If any of these financial institutions fail to perform their obligations under the terms of these financial instruments, the Company's maximum exposure to potential losses would be equal to the amounts reported on the balance sheet.

Segment and Geographic Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations as and manages its business in one operating segment operating exclusively in the United States.

Cash and Cash Equivalents

Cash and cash equivalents consist of investment in money market funds with commercial banks and financial institutions. The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents are stated at amortized cost, plus accrued interest, which approximates fair value.

Marketable securities

Marketable securities consist of debt securities with maturities greater than three months from the date of purchase that include commercial paper and corporate notes. Classification of marketable securities between current and non-current is dependent upon the maturity date at the balance sheet date taking into consideration the Company's ability and intent to hold the investment to maturity. There were no outstanding marketable securities as of December 31, 2023 and 2022.

Interest and dividend income are recorded when earned and included in interest income in the statement of operations. Premiums and discounts, if any, on marketable securities are amortized or accreted to maturity and included in interest income in the statement of operations. The specific identification method is used in computing realized gains and losses on the sale of the Company's marketable securities.

The Company classifies its marketable securities as available-for-sale. The Company determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. Marketable securities that are classified as available-for-sale are measured at fair value on the balance sheet, and unrealized gains and losses on marketable securities are reported as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit) until realized. Marketable securities are evaluated periodically to determine whether the carrying value of a marketable security exceeds its fair value and the decline in value is determined to be other-than-temporary. Management reviews criteria, such as the general market conditions, magnitude and duration in which the fair value has been less than the carrying value, the investment issuer's financial condition and business outlook, as well as the Company's ability to hold the securities until the recovery of its amortized cost basis, to determine whether the decline in value is other-than-temporary. If a decline in value is determined to be other-than-temporary, the value of the marketable security is reduced, and the impairment is recorded as other expense in the statement of operations. As of December 31, 2022, any decline

3. Summary of Significant Accounting Policies (continued)

in value of marketable securities was concluded not to be other-than-temporary. As of December 31, 2023, no assessment was required.

Restricted cash

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

	December 31,	
	2023	2022
Cash and cash equivalents	$ 3,202,452	$ 34,642,340
Restricted cash	20,000	55,000
Total	$ 3,222,452	$ 34,697,340

Amounts included in restricted cash represent amounts required as collateral on corporate credit cards.

Fair value measurements

The Company's financial instruments include cash and cash equivalents, marketable securities, accounts payable, and accrued expenses. The fair values of the cash and cash equivalents, accounts payable and accrued expenses approximated their carrying values as of December 31, 2023 and 2022, due to their short-term maturities. For a description of the fair value of marketable securities, refer to Note 4.

The Company accounts for recurring and nonrecurring fair value measurements in accordance with ASC 820, Fair Value Measurements ("ASC 820"). ASC 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value, and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 – Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2 – Fair value is determined by using inputs, other than Level 1 quoted prices that are directly and indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models that can be corroborated by observable market data.

Level 3 – Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant judgments to be made by a reporting entity.

In instances where the determination of the fair value measurement is based on inputs from different levels of fair value hierarchy, the fair value measurement will fall within the lowest level input that is significant to the fair value measurement in its entirety. The Company periodically evaluates financial assets and liabilities subject to fair value measurements to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC 820 hierarchy.

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Major replacements and improvements that extend the useful lives of assets are capitalized, while general repairs and maintenance are charged to expense as incurred. Property and equipment are depreciated using the straight-line method over the estimated useful lives of

3. Summary of Significant Accounting Policies (continued)

the assets. Leasehold improvements are amortized over the estimated useful lives of the assets or the related lease term, whichever is shorter. Upon retirement or disposal, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is recognized within operating expenses.

The estimated useful lives of property, plant and equipment by major category are as follows:

	Estimated Useful Life
Laboratory equipment	7 years
Computer equipment and software	3 years
Furniture and fixtures	7 years
Leasehold Improvements	Shorter of lease term or useful life

Impairment of long-lived assets

The Company evaluates the carrying value of its long-lived asset group for potential impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Recoverability is determined by comparing future undiscounted cash flows associated with such assets to the related carrying value. An impairment loss may be recognized when the estimated undiscounted future cash flow is less than the carrying amount of the asset. If these cash flows are less than the carrying value of such asset group, the Company then determines the fair value of the underlying asset group. Any impairment loss to be recognized is measured as the amount by which the carrying value of the asset group exceeds the fair value of the asset group. Based on the analysis performed by management, the Company expensed $0.1 million of property and equipment as impaired as of December 31, 2023 to other expense. No impairments were recognized for the years ended December 31, 2022.

Loss on assets held for sale

Loss on assets held for sale is the difference between the asset's estimated fair value less estimated costs to sell and the asset's book value at the time the asset is no longer used for operations and reclassified as held for sale in accordance with the held-for-sale criteria.

Research and development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including share-based compensation, as well as costs for third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, based on its estimates of services performed and costs incurred. These estimates include the level of services performed by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expenses in future periods as the related services are rendered.

Clinical trial and contract development and manufacturing organization expenses

The Company makes payments in connection with clinical trials and contract development and manufacturing organizations ("CDMO") under contracts with contract research organizations that support conducting and managing clinical trials and the manufacturing of materials utilized in clinical and preclinical activities. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of the obligation to make payments under these contracts depends on factors such as the successful enrollment, treatment of patients, the completion of other clinical trial milestones, or completion of manufacturing milestones. Termination clauses

3. Summary of Significant Accounting Policies (continued)

within the agreements require notification for a certain number of days prior to completing work, payments for costs incurred through the termination date, and termination penalty, if applicable.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. Expenses related to development and manufacturing are accrued based on estimates and/or representations from service providers regarding work performed, including progress in the development of processes through technology transfers to manufacture the Company's clinical material and completion of the manufactured clinical material. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts the Company is obligated to pay under clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the accruals are adjusted accordingly. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Stock-based compensation

The Company records compensation expense associated with stock options and other forms of equity compensation based on the estimated fair value at the grant date. Compensation expense related to awards to employees and non-employees with service based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the requisite service period of the award, which is generally the vesting term. The Company's policy is to account for forfeitures as they occur. The Company uses the Black-Scholes-Merton option pricing, or Black-Scholes, model to estimate the fair value of stock options. The Black-Scholes model requires input-based assumptions that are highly subjective, judgmental and sensitive in the determination of stock-based compensation cost.

Options granted after the Company's Initial Public Offering, or IPO, are issued at the fair market value of the Company's common stock at the date the grant is approved by the Board of Directors.

Expected volatility—The expected volatility was based on the historical volatility of comparable public companies from a representative peer group selected based on industry and market capitalization data. The historical volatility is calculated based on a period of time commensurate with the expected term assumption.

Risk-free interest rate—The risk-free interest rate was based on the continuous rates provided by the U.S. Treasury with a term approximating the expected term of the option.

Expected dividend yield—The expected dividend yield was 0% because the Company has not historically paid and does not expect to pay any dividends for the foreseeable future.

Expected term—The Company uses the simplified method as prescribed by the Securities and Exchange Commission, or the SEC, Staff Accounting Bulletin No. 107, Share-Based-Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

See Note 12 for a further discussion on stock-based compensation.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. 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 income in the period that includes the enactment date. Deferred tax expense or benefit is the result of changes in deferred tax assets and liabilities.

3. Summary of Significant Accounting Policies (continued)

Valuation allowances are established when necessary to reduce deferred tax assets where, based upon the available evidence, the Company concludes it is more-likely-than-not that the deferred tax assets will not be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available positive and negative evidence, including its operating results, on-going tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. The Company recorded a valuation allowance against all estimated net deferred tax assets as of December 31, 2023 and 2022.

Liabilities are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. Recognized income tax positions are measured at the largest amount that is greater than more-likely-than-not of being realized. Changes in the recognition or measurement are reflected in the period in which the change in estimate occurs. Interest and penalties related to uncertain tax positions are recorded in the provision of income taxes. There were no uncertain tax positions nor income tax related interest and penalties recorded as of or for the years ended December 31, 2023 and 2022.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common stock and common stock equivalents outstanding for the period. The Company adjusts net loss to arrive at the net loss attributable to common stockholders to reflect the amount of dividends accumulated during the period on the Company's redeemable convertible preferred stock. Such dividends are only payable if and when declared by the Board of Directors (Note 11). The treasury stock method is used to determine the dilutive effect of the Company's stock option grants. For the years ended December 31, 2023 and 2022, the Company had a net loss attributable to common stockholders, and as such, all outstanding stock options and RSUs were excluded from the calculation of diluted loss per share. The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2023 and 2022:

	2023	2022
Net loss	$ (32,344,393)	$ (62,506,199)
Net loss attributable to common stockholders	$ (32,344,393)	$ (62,506,199)
Basic and diluted net loss per common share	$ (30.82)	$ (64.95)
Basic and diluted weighted average common shares outstanding	1,049,468	962,364

The following potentially dilutive securities have been excluded from the computation of diluted weighted average common shares outstanding at December 31, 2023 and 2022, as the effect would be anti-dilutive:

	2023	2022
Stock options	130,526	158,620
Restricted stock units	26,460	62,320
Total	156,986	220,940

Emerging growth company status

The Company is an "emerging growth company" (EGC), as defined in the Jumpstart Our Business Startups Act (JOBS Act), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards, and as a result of this election, the financial statements may not be comparable to companies that comply with public company FASB standards' effective dates. The

3. Summary of Significant Accounting Policies (continued)

Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of an IPO offering or such earlier time that it is no longer an EGC.

Recent accounting standards and pronouncements

Recently Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326) ("ASU 2016-13"), which modifies the measurement of expected credit losses on certain financial instruments. In addition, for available-for-sale debt securities, the standard eliminates the concept of other-than-temporary impairment and requires the recognition of an allowance for credit losses rather than reductions in the amortized cost of the securities. The standard is effective for fiscal year beginning after December 15, 2022 and interim periods beginning after December 15, 2022 and requires a modified-retrospective approach with a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period. Early adoption is permitted. Based on the composition of the Company's investment portfolio, current market conditions and historical credit loss activity, the adoption of ASU 2016-13 did not have a material impact on the Company's financial position, results of operations or the related disclosures. The Company adopted the new guidance on January 1, 2023 and determined there was no impact.

Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06—Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative, to clarify or improve disclosure and presentation requirements of a variety of Topics. ASU 2023-06 adds 14 of the 27 identified disclosure or presentation requirements to the Codification. However, each amendment in the ASU will only become effective if the SEC removes the related disclosure or presentation requirement from its existing regulations by June 30, 2027. The effective dates of ASU 2023-06 will depend, in part, on whether an entity is already subject to the SEC's current disclosure requirements. For such entities and those that must "file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer," the effective date for each amendment will be the date on which the SEC's removal of that related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years after the date of such removal. The Company is currently assessing the effect of this ASU on its financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07—Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, to improve the disclosures about a public entity's reportable segments and address requests from investors for additional, more detailed information about a reportable segment's expenses. All public entities will be required to report segment information in accordance with the new guidance starting in annual periods beginning after December 15, 2023. The Company plans to adopt the ASU for the fiscal year beginning January 1, 2024. Since the Company has only one reportable segment, the Company will need to disclose the title and position of the chief operating decision maker ("CODM") and an explanation of how the CODM uses the reported measures of segment profit or loss in assessing segment performance and deciding how to allocate resources, as well as disclose, on an annual and interim basis, significant segment expenses that are regularly provided to the CODM. The Company is currently assessing the effect of this ASU on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09—Income Taxes (Topic 740): Improvements to Income Tax Disclosures, to address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information as well as certain other amendments to improve the effectiveness of income tax disclosures. The amendments in this update are effective for annual periods beginning after December 15, 2024. The Company does not expect adoption of this ASU to have a material impact on its results of operations, financial condition, and its financial statements other than adding new disclosures, which the Company is currently evaluating, as the Company has not recorded any net tax provision for the periods presented due to the losses incurred and the need for a full valuation allowance on net deferred tax assets.

3. Summary of Significant Accounting Policies (continued)

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements and related disclosures upon adoption.

4. Fair Value Measurements

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis:

	December 31, 2023			December 31, 2022		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds	$ 23,270	$ —	$ —	$ 23,722,328	$ —	$ —
Fixed income debt securities	$ —	$ —	$ —	$ —	$ 7,979,279	$ —
	$ 23,270	$ —	$ —	$ 23,722,328	$ 7,979,279	$ —

During the years ended December 31, 2023 and 2022, the Company did not have any transfers between levels. There were no Level 3 recurring fair value measurements as of December 31, 2023 or 2022.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following at December 31, 2023 and 2022:

	2023	2022
Prepaid research and development expenses	$ 115,353	$ 1,176,491
Prepaid maintenance agreements	—	369,606
Prepaid insurance	368,048	403,653
Prepaid other	35,817	245,278
Interest receivable	—	74,467
Other current assets	215,246	401,916
	$ 734,464	$ 2,671,411

6. Property and Equipment

In November 2023, the Company terminated its primary lease and began moving equipment from its facility to be sold. The Company considered the criteria to classify the property and equipment as held for sale under ASC 360—Property, plant and equipment (Topic 360). Assets shall be classified as held for sale in the period in which all of the following criteria are met: a) Management commits to a plan to sell the entity to be sold. b) The assets to be sold are available for immediate sale in its present condition. c) An active program to locate a buyer or buyers is in place. d) The sale is probable, and is expected to be completed within one year. e) The assets to be sold being actively marketed for sale at a price that is reasonable in relation to its current fair value. f) Actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn. The Company determined that all these criteria as of December 31, 2023 were met for certain categories of the property and equipment, specifically certain computers and laboratory equipment. Accordingly, the computers and laboratory equipment being sold were classified as current assets held for sale at December 31, 2023. See Note 7 for discussion on the Assets Held for Sale.

Property and equipment consist of the following at December 31, 2023 and 2022:

	2023	2022
Laboratory equipment	$ 2,668,280	$ 6,803,996
Computer equipment and software	202,963	516,974
Furniture and fixtures	—	47,877
Leasehold improvements	36,459	319,816
	2,907,702	7,688,663
Less accumulated depreciation and amortization	(1,554,801)	(3,229,592)
Property and equipment, net	$ 1,352,901	$ 4,459,071

Depreciation and amortization expense was $1.0 million for both years ended December 31, 2023 and 2022, respectively.

7. Assets Held For Sale

On November 29, 2023, the Company and AFAB Lab Resources, LLC (“AFAB”) initiated an asset sales agreement, pursuant to which AFAB would sell certain computers and laboratory equipment. According to Topic 360, the Company determined that the criterion to classify the certain computers and laboratory equipment as assets held for sale within the Company’s balance sheet effective as of December 31, 2023 were met. Accordingly, the assets were classified as current assets held for sale as of December 31, 2023 as the Company, at that time, expected to sell these assets within the next twelve months.

The classification to assets held for sale impacted the net book value of the assets expected to be transferred upon sale. The estimated fair value of the computers and laboratory equipment was determined using the purchase price in the purchase agreement along with estimated broker, accounting, legal, and other selling expenses, which resulted in the lower of the carrying value and the fair value less costs to sell of approximately $1.4 million. The carrying value of the assets being classified as held for sale was approximately $2.0 million. As a result, the Company recorded a loss on assets held for sale of $0.7 million. Upon completion of the computers and laboratory equipment sales, the Company could record an additional gain or loss on disposal at the time final net proceeds are determined. Additionally, the expected sale of assets held for sale was not deemed to represent a fundamental strategic shift that would have a major effect on the Company’s operations, and accordingly, it was not reported as discontinued operations in the Company’s statement of operations for the year ended December 31, 2023.

8. Restructuring Activities

In November 2022, the Company announced that, following a strategic review of its pipeline, indications, timelines and cash position, it implemented a strategic realignment initiative, which was designed to reduce costs and reallocate resources towards its AIM INJ preclinical development programs. As part of this strategy, the Company initiated a workforce reduction plan to reduce headcount by 30%, primarily affecting the clinical development, manufacturing and administrative staff that had been needed to support the AIM ACT adoptive cell therapy clinical programs. This plan reduced the Company's workforce from 74 full-time employees to approximately 50 full-time employees. The Company incurred approximately $0.7 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. These one-time employee termination benefits are comprised of severance, benefits and related costs, all of which are resulted in cash expenditures.

In August and October 2023, the Company announced that, in order to reduce its cash expenditures while continuing to pursue its existing strategic plan, its Board of Directors approved and its management is implementing a reduction in workforce, designed to reduce costs and extend the Company's cash. The realignment reduced the Company's workforce from 44 to 6 full-time employees. The Company incurred $3.1 million of costs in connection with the reductions in workforce related to severance pay and other related termination benefits. These one-time employee termination benefits are comprised of severance, benefits and related costs, and are recorded to research and development and general administrative expenses, all of which are expected to result in cash expenditures. The Company expects that the implementation of the reduction-in-force will be substantially complete in September 2024.

Accrued salaries at December 31, 2022 includes $0.4 million in severance expenses related to the November 2022 restructuring. The Company communicated the workforce reduction on November 14, 2022 and recognized $0.5 million in costs associated with the restructuring during the year ended December 31, 2022. The Company completed these restructuring in the second quarter of 2023.

The following table summarizes the charges related to the restructuring activities as of December 31, 2023 and December 31, 2022.

	Accrued Restructuring Expenses December 31, 2022	Expenses	Less: Payments	Accrued Restructuring Expenses December 31, 2023
Severance, benefits and related costs due to workforce reduction	$ 382,389	$ 3,090,371	$ (3,206,223)	$ 266,537
Totals	$ 382,389	$ 3,090,371	$ (3,206,223)	$ 266,537

	Accrued Restructuring Expenses December 31, 2021	Expenses	Less: Payments	Accrued Restructuring Expenses December 31, 2022
Severance, benefits and related costs due to workforce reduction	$ —	$ 531,829	$ (149,440)	$ 382,389
Totals	$ —	$ 531,829	$ (149,440)	$ 382,389

9. Accrued Expenses and other current liabilities

A summary of the components of accrued expenses is as follows as of December 31, 2023 and 2022:

	2023	2022
Accrued research and development costs	$ 3,148,021	$ 3,210,794
Accrued professional fees	131,226	267,383
Accrued salaries, benefits and related expenses	389,858	3,855,797
Other accrued expenses and other current liabilities	10,000	23,179
Total	$ 3,679,105	$ 7,357,153

10. Commitments and Contingencies

The Company entered into a Translational Research Award Agreement effective May 23, 2012 with the Department of Business & Economic Development with the State of Maryland, Maryland Biotechnology Center ("MBC"). The mission of MBC is to integrate entrepreneurial strategies to stimulate the transformation of scientific discovery and intellectual assets into capital formation and business development. Under the agreement, MBC provided $200,000 to NexImmune for research on its artificial aAPC for cancer immunotherapy. In 2013, an amendment increased the amount by $125,000 for a total grant of $325,000. This grant was recorded as income in 2012 and 2013, as the Company incurred the expenses which qualified it for the grant.

The Company must repay the funds through annual payments calculated at 3% of annual revenues for the preceding year. Payments shall continue for 10 years after the first payment date and may total up to 200% of the total grant amount. The end date of the agreement is defined as January 31, 2024, or when any and all repayments due to MBC have been made. If the Company does not earn any revenue, the grant does not need to be repaid. Through December 31, 2023, no revenue has been recorded, therefore, no payments to MBC are due.

Johns Hopkins University Exclusive License Agreement

The Company entered into an Exclusive License Agreement with Johns Hopkins University ("JHU") effective June 2011, which was amended and restated in January 2017, referred to as the A&R JHU License Agreement, under which there are license fees, royalties, and milestone payments. As part of the agreement, the Company acquired a perpetual, exclusive license from JHU covering its invention related to Antigen Specific T cells.

JHU was also entitled to milestone fees of $75,000 in connection with clinical trial milestones. For the first licensed product or licensed service in the therapeutic field, the Company may be required to pay JHU additional aggregate milestone fees of $1.6 million for clinical and regulatory milestone fees. The Company may be required to pay JHU reduced milestone fees for the second and third licensed products or licensed services in the therapeutic field in connection with clinical and regulatory milestones. In the diagnostic field, the Company may be required to pay JHU aggregate milestone fees of $0.4 million for the first licensed product or licensed service and reduced milestone fees for the second and third licensed products or licensed services in connection with regulatory and commercial milestones. The Company may be required to pay JHU aggregate milestone fees of $100,000 for commercial milestones for the first licensed product or licensed service in the non-clinical field. In the aggregate, the Company may be required to pay JHU additional milestone fees of up to $4.2 million for all clinical, regulatory and commercial milestones for all licensed products or licensed services in the therapeutic field, the diagnostic field and the non-clinical field. The Company may also be required to pay royalties in the low to upper single digits on net sales of licensed services in therapeutic products, diagnostic products and non-clinical products. The Company is required to make minimum annual royalty payments of $100,000 to JHU under the A&R JHU License Agreement, which started in the low five figures in the first year of the agreement and increased to $100,000 in the third year and for each subsequent year of the agreement. The Company may also be required to pay JHU a low double digit percentage, not to exceed 15%, of any non-royalty sublicense consideration the Company receives.

10. Commitments and Contingencies (continued)

The Company will record a liability when such events become probable. The Company has not reached any of the milestones or transacted its first commercial sale as of December 31, 2023.

The Company must make minimum royalty payments, which began upon the fourth anniversary of the agreement and upon every anniversary thereafter during the term of the agreement, which offset future royalties per above owed to JHU.

The Company has incurred $625,000 in cumulative minimum royalties from inception. Future annual minimum royalties consist of $100,000 due each year during the remaining term of the agreement. The Company records milestones, royalties and minimum royalties at the time when payments become probable. The Company incurred $100,000 related to minimum royalties owed in the years ended December 31, 2023 and 2022 and is included in research and development expenses on the accompanying statement of operations. The Company has accrued royalties of $50,000 as of December 31, 2023 and 2022.

Contingencies

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. As of December 31, 2023 and 2022, the Company was not involved in any material legal proceedings.

11. Stockholders' Equity

The Company had 250,000,000 authorized shares of common stock, par value $0.0001 per share, of which 1,066,320 and 1,043,138 shares were issued and outstanding at December 31, 2023 and 2022, respectively.

Issuances of Common Stock

On March 9, 2022, the Company filed a shelf registration statement on Form S-3, or the Form S-3, with the SEC pursuant to which we disclosed that we may offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, debt securities, warrants, rights or units having a maximum aggregate offering price of $200 million.

On June 17, 2022, the Company entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and BTIG, LLC (together, the "Agents"), pursuant to which the Company may offer and sell shares of its common stock, $0.0001 par value per share, having an aggregate offering price of up to $50.0 million (the "Shares") from time to time through the Agents (the "Offering"). Subject to the terms and conditions of the Sales Agreement, any such sales made through the Agents can be made, based upon the Company's instructions, by methods deemed an "at-the-market" offering as defined in Rule 415(a)(4) promulgated under the Securities Act. The Company agreed to pay the Agents a commission of 3.0% of the gross proceeds of any sales of shares sold pursuant to the Sales Agreement. During the year ended December 31, 2022, the Company sold an aggregate of 127,396 shares through our "at-the-market" offering facility resulting in net proceeds of $5.1 million. No sales were transacted for the year ended December 31, 2023. On February 2, 2024, the Company and each of the Agents mutually agreed to terminate the Sales Agreement effective immediately. The Company did not incur any material early termination penalties in connection with the termination of the Sales Agreement.

On February 2, 2024, the Company and each of the Agents mutually agreed to terminate the Sales Agreement and the ATM Program effective immediately. The Company did not incur any material early termination penalties in connection with the termination of the Sales Agreement.

On February 2, 2024, the Company, entered into a securities purchase agreement (the "Purchase Agreement") with a single healthcare focused institutional investor (the "Investor"), pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market (the "Registered Offering"), (i) an aggregate of 117,000 shares (the "Shares") of common stock, par value $0.0001, of the Company (the "Common Stock"), at an offering price of $12.05 per share, and (ii) pre-funded warrants (the "Pre-Funded Warrants") exercisable for up to 187,731 shares of Common Stock (the "Pre-Funded Warrant Shares"), at an offering price of $12.049 per Pre-Funded Warrant, for aggregate gross proceeds from the Offerings (as defined below) of approximately $3.7 million before deducting the placement

11. Stockholders' Equity

agent fee (as described in greater detail below) and related offering expenses. The closing of the Offerings is expected to occur on or about February 6, 2024, subject to the satisfaction of customary closing conditions.

The shares of Common Stock and Pre-Funded Warrants (and shares of common stock underlying the Pre-Funded Warrants) were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-263399), which was filed with the Securities and Exchange Commission (the "SEC") on March 9, 2022 and declared effective by the SEC on March 16, 2022 ("Registration Statement"), including the base prospectus contained therein, and a related prospectus supplement, dated February 2, 2024, filed with the SEC on February 5, 2024.

In a concurrent private placement (the "Private Placement" and, together with the Registered Offering, the "Offerings"), the Company issued to the Investor unregistered warrants to purchase up to an aggregate of 304,731 shares of Common Stock (the "Unregistered Warrants") at an exercise price of $12.05 per share. Each Unregistered Warrant is exercisable immediately and will expire two years from the initial exercise date. The Unregistered Warrants and the shares of our Common Stock issuable upon the exercise of the Unregistered Warrants are not being registered under the Securities Act of 1933, as amended (the "Securities Act"), are not being offered pursuant to the Registration Statement and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act, and/or Rule 506(b) promulgated thereunder.

12. Stock-Based Compensation

During January 2017, the Company adopted the 2017 Equity Incentive Plan (the "2017 Plan"), which provides for granting of restricted stock, options to purchase shares of common stock and other awards to employees, directors and consultants. In March 2017, the Company amended the 2017 Plan to increase the number of available shares to 26,433. In September 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan") which provides for granting of restricted stock, options to purchase shares of common stock, and other awards to employees, directors and consultants, and reserved 69,670 shares for this purpose. The 2018 Plan was amended in July 2018 to increase the number of available shares to 72,365. In February 2021, the Company adopted the 2021 Equity Incentive Plan ("2021 Plan") and reserved 110,302 shares under the plan. No further shares will be issued under the 2017 and 2018 plans. In addition, the 2021 Plan contains an "evergreen" provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the 2021 Plan on the first day of each calendar year beginning in calendar year 2022. The annual increase in the number of shares shall be equal to the lower of (i) 5.0% of the number of shares of our common stock outstanding on the date of the applicable increase or (ii) a lesser amount determined by our board of directors. Following the annual increase in the number of shares of our common stock available for issuance under the 2021 Plan, there are 152,533 shares available for issuance under the 2021 plan as of March 1, 2024.

The number of options to be granted under the 2021 Plan, the option exercise prices, and other terms of the options are determined by the Board of Directors in accordance with the terms of the 2021 Plan. Generally, stock options are granted at fair value, become exercisable over a period of one to four years, expire in ten years or less and are subject to the employee's continued employment. Restricted stock units awarded in November 2022 vest after an 18-month service period. No restricted stock units were awarded in the year ended December 31, 2023.

On March 22, 2023, in order to retain and motivate employees and other key contributors of the Company, the Board approved a one-time stock option repricing, or the Option Repricing. Pursuant to the Option Repricing, the exercise price of all of the below stock options to purchase shares of the Company's common stock previously granted under our 2017 Plan, 2018 Plan and 2021 Plan, or the Repriced Options, was amended as of April 4, 2023 or the Effective Date, to reduce the exercise prices of such options to a price equal to or greater than the closing price per share of the Company's common stock on The

12. Stock-Based Compensation (continued)

Nasdaq Stock Market on the Effective Date, which was $0.41 per share, or the "Nasdaq Market Price", on the terms described below:

Repriced Options	Terms of Repriced Options vested or vesting within six months following the Effective Date	Terms of Repriced Options vesting more than six months following the Effective Date
All options held by employees other than our executive officers, in good standing on the Effective Date	The Option Repricing exercise price will be equal to 2.5 times the Nasdaq Market Price, or $25.75	The Option Repricing exercise price will be equal to the Nasdaq Market Price, or $10.25.
All options held by our current executive officers and 100,000 options held by Jerome Zeldis, our former Executive Vice President and Head of Research & Development	The Option Repricing exercise price will be equal to 3.0 times the Nasdaq Market Price, or $30.75.	The Option Repricing exercise price will be equal to 2.0 times the Nasdaq Market Price, or $20.50.
All options held by our directors	The Option Repricing exercise price will be equal to 4.0 times the Nasdaq Market Price, or $41.00.	The Option Repricing exercise price will be equal to 3.0 times the Nasdaq Market Price, $30.75.

The Company treated the Option Repricing as a modification to the original stock option grant because the terms of the agreements were modified. The total number of options issued and outstanding were not impacted by the Option Repricing.

The calculation of the incremental compensation expense is based on the excess of the fair value of the award measured immediately before and after the modification. The total incremental expense calculated to be recognized over the service period is $0.3 million. As a result, the Company recognized an incremental compensation expense for vested shares $0.2 million associated with the modification arising from the Option Repricing for the year ended December 31, 2023.

Stock-based compensation expense was recorded in the following financial statement line items within the statement of operations for the years ended December 31, 2023 and 2022:

	2023	2022
Research and development expenses	$ 1,133,428	$ 3,812,441
General and administrative expenses	2,420,198	2,057,923
Total stock-based compensation expense	$ 3,553,626	$ 5,870,364

As a result of the August and November 2023 reduction in force actions, certain executives' options accelerated vesting that resulted in an expense of $0.6 million for the year ended December 31, 2023.

12. Stock-Based Compensation (continued)

The following is a summary of option activity under the Company's Stock Option Plans:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($ millions)
Outstanding as of January 1, 2023	158,620	$ 184.51	8.0	$ —
Granted	46,644	9.44		
Exercised	—	—		
Cancelled	(53,271)	172.1		
Forfeited	(21,467)	61.18		
Outstanding as of December 31, 2023	130,526	$ 28.64	7.3	$ —
Vested or expected to vest as of December 31, 2023	130,526	$ 28.64	7.3	$ —
Exercisable as of December 31, 2023	78,536	$ 38.73	6.3	$ —
Shares unvested as of December 31, 2023	52,030	$ 13.95	8.9	$ —

The weighted average fair value of the options granted during the years ended December 31, 2023 and 2022 was $7.17 and $60.50, respectively. The options were valued using the Black-Scholes option-pricing model for the years ended December 31, 2023 and 2022 with the following assumptions:

	2023	2022
Expected volatility	90.2% to 93.7%	78.6% to 83.2%
Risk-free interest rate	3.4% to 4.20%	1.5% to 3.80%
Expected dividend yield	0%	0%
Expected term	5.5 to 6.1 years	5.5 to 6.1 years

The total fair value of stock options vested during the years ended December 31, 2023 and 2022 was $2.2 million, and $9.2 million, respectively. The intrinsic value of stock options exercised for the years ended December 31, 2023 and 2022 was approximately zero and $0.2 million, respectively.

As of December 31, 2023, there was $1.9 million of total unrecognized compensation expense related to unvested options that will be recognized over a weighted average period of 1.9 years.

Restricted Stock Units

A restricted stock unit, or RSU, represents the right to receive one of the Company's common stock upon vesting of the RSU. The fair value of each RSU is based on the closing price of the Company's common stock on the date of grant.

12. Stock-Based Compensation (continued)

The following is a summary of RSU activity for the 2021 Plan for the year ended December 31, 2023:

	Number of restricted units	Weighted average grant date fair value
Unvested and outstanding at January 1, 2023	62,320	$ 11.30
Granted	—	—
Settled	(31,044)	11.25
Forfeited	(4,816)	11.25
Unvested and outstanding as of December 31, 2023	26,460	$ 11.36

As of December 31, 2023, there was $0.1 million of unrecognized compensation expense related to unvested RSUs, which are expected to be recognized over a weighted average period of 0.4 years.

13. Income Taxes

The Company's provision for income taxes consists of the following for the years ended December 31, 2023 and 2022:

	2023	2022
Current income tax provision:		
Federal	$ —	$ —
State	—	—
Total	—	—
Deferred income tax benefit:		
Federal	4,967,519	12,339,546
State	15,852	(7,370,113)
Total	4,983,371	4,969,433
Change in valuation allowance	(4,983,371)	(4,969,433)
Total provision (benefit) for income taxes	$ —	$ —

A reconciliation of the statutory U.S. income tax rate to the effective income tax rate as of December 31, 2023 and 2022 is as follows:

	2023	2022
U.S. Federal statutory rate	21.00 %	21.00 %
State taxes	0.20 %	0.17 %
Permanent differences	(0.89)%	(0.58)%
Other adjustments	(4.81)%	(0.02)%
Change in state tax rate	0.01 %	(12.61)%
Change in valuation allowance	(15.51)%	(7.96)%
Provision for income taxes	0.00 %	0.00 %

13. Income Taxes (continued)

The significant components of the Company's deferred tax assets (liabilities) as of December 31, 2023 and 2022 were as follows:

	2023	2022
Deferred tax assets:		
Net operating loss carryforward	$ 32,486,609	$ 28,477,866
Accrued compensation	542,591	575,883
Stock compensation	825,801	1,913,771
Research and development credits	291,022	291,022
Capitalized research and development costs	9,826,015	7,838,512
Operating leases	14,587	216,925
Other	2,025	2,022
Gross deferred income tax assets	43,988,650	39,316,001
Less: Valuation allowance	(43,840,838)	(38,857,468)
Total deferred income tax assets	147,812	458,533
Deferred tax liabilities:		
ROU assets	(9,903)	(204,694)
Depreciation and amortization	(137,909)	(253,839)
Total deferred tax liabilities	(147,812)	(458,533)
Net deferred tax assets	$ —	$ —

At December 31, 2023 and 2022, the Company had net operating loss (NOL) carryforwards for income tax purposes of approximately $154.3 million and $135.2 million, respectively, which are available to offset future federal taxable income, if any. Approximately $10.5 million of the federal NOL was generated prior to 2018 and will be expiring in increments through 2037 beginning in 2035, while the remaining $143.8 million will be carried forward indefinitely, with a limitation of 80% of taxable income. The state NOL will expire in increments through 2037, beginning in 2035. The federal research and development tax credit carryforwards, if not utilized, will expire beginning in 2037.

Section 382 of the Internal Revenue Code imposes substantial restrictions on the utilization of net operating losses and Section 383 of the Internal Revenue Code imposes restrictions on the utilization of tax credits in the event of a corporations' ownership change. The Company believes that the future use of net operating losses and tax credits presented above may be limited as a result of past ownership changes and a formal study has not yet been completed.

The Company recognizes the effect of income tax positions only if those positions more likely than not of being sustained. At December 31, 2023, the Company had no gross unrecognized tax benefits and did not recognize any interest or penalties related to uncertain tax positions.

At December 31, 2023, the Company provided a 100% valuation allowance on its net deferred tax assets because realization of any future tax benefit cannot be reasonably assured. The Company's valuation allowance increased due to the pre-tax losses generated in the current year.

The Company is subject to income taxation by both federal and state taxing authorities. Due to the net operating loss and tax credit carryforward, tax years 2015 through 2023 remain open to examination by the major taxing jurisdictions to which the Company is subject. There are no open examinations that would have a meaningful impact to the consolidated financial statements.

Under the Tax Cuts and Jobs Act of 2017, research and development costs are no longer fully deductible and are required to be capitalized and amortized for US Tax purposes over five or fifteen years effective January 1, 2022. The mandatory capitalization requirement increased our deferred tax assets as of December 31, 2023 and 2022.

14. Leases

The Company leases certain office space and laboratory space. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. The Company does not recognize right-of-use assets or lease liabilities for leases determined to have a term of 12 months or less. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

At the lease commencement date, the operating lease liability is recorded at the present value of future lease payments over the expected remaining lease term using the discount rate implicit in the lease, if it is readily determinable, or the Company's incremental borrowing rate. The right-of-use asset is measured as the lease liability and adjusted for prepaid rent, initial direct costs, and incentives. The Company's leases contain variable non-lease components such as maintenance, taxes, insurance, and similar costs for the spaces it occupies. For new and amended leases beginning in 2022 and after, the Company has elected the practical expedient not to separate these non-lease components of leases for classes of all underlying assets and instead account for them as a single lease component for all leases. The Company recognizes the net fixed payments of operating leases on a straight-line basis over the lease term. Variable executory costs, as it relates to net leases, are to be excluded from the calculation of the lease liability and the Company expenses the variable lease payments in the period in which it incurs the obligation to pay such variable amounts and will be included in variable lease costs in the leases footnote disclosure.

On November 1, 2023, the Company terminated its lease at 9119 Gaither Rd., Gaithersburg, Maryland. The termination date is January 31, 2024. Management accounted for this change to the lease as a lease modification that shortens the lease term. The effect of the modification as of December 31, 2023 was $0.4 million.

Variable lease payments are not included in the Company's calculation of its right-of-use assets or lease liabilities. Variable lease costs were immaterial for the year ended December 31, 2023. The components of lease cost under ASC 842 for the year ended December 31, 2023 are as follows:

Lease costs	Statement of Operations Classification	December 31, 2023	December 31, 2022
Operating lease cost	Operating expenses: research and development	$ 331,215	$ 379,288
Operating lease cost	Operating expenses: general and administrative	228,354	207,401
		$ 559,569	$ 586,689

Supplemental disclosure of cash flow information and weighted average remaining lease term and discount rate related to leases were as follows:

Other information	December 31, 2023	December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ (617,999)	$ (584,429)
Right-of-use assets in exchange for operating lease liabilities	$ (382,910)	$ —
Weighted-average remaining lease term — operating leases	0.1 years	1.8 years
Weighted-average discount rate — operating leases	6.7 %	6.8 %

Future fixed lease payments for operating leases in effect as of December 31, 2023, are payable as follows:

14. Leases (continued)

Maturity of lease liabilities for the years ending December 31,		Operating Leases
2024	$	68,898
2025		—
2026		—
2027		—
2028		—
Thereafter		—
Total lease payment	$	68,898
Less: imputed interest		(89)
Present value of lease liabilities	$	68,809

15. Related Party Transactions

On March 16, 2022, the Company and Zephyr AI, Inc. (“Zephyr”) entered into a Joint Research Agreement (the “JRA”) focused on the joint collaboration, identification and validation of certain targets in order to facilitate further research, development and potential commercialization of immunotherapies. Zephyr is owned by a holding company with multiple Board members from the Company. The JRA term is two years unless mutually extended. As of March 16, 2024, neither party extended the JRA and the JRA is terminated. The expenses related to the JRA for the year ended December 31, 2023 and 2022 were not material.

Beginning in June 2022, the Company entered into a series of statement of works with the Center for Discovery & Innovation at Hackensack Meridian Health ("CDI") to enhance the Company's AIM platform. The Chairman of the Board of CDI is a Board member. The total value of the statement of works through July 31, 2023 is $0.2 million. The expenses incurred to the CDI for the years ended December 31, 2023 and 2022 was $0.1 million and $40,000, respectively. The Company has recorded a $25,000 accrual as of December 31, 2023.

16. Subsequent Events

Not applicable

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8 No. 333-253527) pertaining to the 2017 Equity Incentive Plan, as amended, the 2018 Equity Incentive Plan, as amended, and the 2021 Equity Incentive Plan of NexImmune, Inc.,
2. Registration Statement (Form S-3 No. 333-263399) of NexImmune, Inc.,
3. Registration Statement (Form S-8 No. 333-263400) pertaining to the 2021 Equity Incentive Plan of NexImmune, Inc., and
4. Registration Statement (Form S-8 No. 333-270906) pertaining to the 2021 Equity Incentive Plan of NexImmune, Inc.

of our report dated April 16, 2024, with respect to the financial statements of NexImmune, Inc. included in this Annual Report (Form 10-K) of NexImmune, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Tysons, Virginia
April 16, 2024

Exhibit 31.1

CERTIFICATION UNDER SECTION 302

I, Kristi Jones, certify that:

1. I have reviewed this annual report on Form 10-K of NexImmune, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 16, 2024

By: /s/ Kristi Jones

Kristi Jones
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION UNDER SECTION 302

I, Timothy Stover, certify that:

1. I have reviewed this annual report on Form 10-K of NexImmune, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 16, 2024

By: /s/ Timothy Stover

Timothy Stover
Vice President, Corporate Controller
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of NexImmune, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge that:

The Annual Report for the year ended December 31, 2023 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 16, 2024

By: /s/ Kristi Jones

Kristi Jones
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of NexImmune, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge that:

The Annual Report for the year ended December 31, 2023 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 16, 2024

By: /s/ Timothy Stover

Timothy Stover
Vice President, Corporate Controller
(Principal Financial Officer and Principal Accounting Officer)

NEXIMMUNE, INC.

CLAWBACK POLICY

I. Introduction

The Board of Directors (the "**Board**") of NexImmune, Inc. (the "**Company**") believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board has therefore adopted this policy which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") and final rules and amendments adopted by the Securities and Exchange Commission (the "**SEC**") to implement the aforementioned legislation.

II. Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

III. Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC and any national securities exchange on which the Company's securities are listed, and such other employees who may from time to time be deemed subject to the Policy by the Board ("**Covered Executives**").

IV. Incentive-Based Compensation

For purposes of this Policy, incentive-based compensation ("**Incentive-Based Compensation**") includes any compensation that is granted, earned, or vested based wholly or in part upon the attainment of any financial reporting measures that are determined and presented in accordance with the accounting principles ("**GAAP Measures**") used in preparing the Company's financial statements and any measures derived wholly or in part from such measures, as well as non-GAAP Measures, share price, and total shareholder return (collectively, "**Financial Reporting Measures**"); however, it does not include: (i) base salaries; (ii) discretionary cash bonuses; (iii) awards (either cash or equity) that are solely based upon subjective, strategic or operational standards or standards unrelated to Financial Reporting Measures, and (iv) equity awards that vest solely on completion of a specified employment period or without any performance condition. Incentive-Based Compensation is considered received in the fiscal period during which the applicable reporting measure is attained, even if the payment or grant of such award occurs after the end of that period. If an award is subject to both time-based and performance-based vesting conditions, the award is considered received upon satisfaction of the performance-based conditions, even if such an award continues to be subject to the time-based vesting conditions.

For the purposes of this Policy, Incentive-Based Compensation may include, among other things, any of the following:

- Annual bonuses and other short- and long-term cash incentives.
- Options to purchase shares of common stock or other equity securities.
- Stock appreciation rights.
- Restricted stock or restricted stock units.
- Performance shares or performance units.

For purposes of this Policy, Financial Reporting Measures may include, among other things, any of the following:

- Company share price.
- Total shareholder return.
- Revenues.
- Net income.

- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

V. Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that (i) is material to the previously issued financial statements or (ii) is not material to previously issued financial statements, but that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Board will require reimbursement or forfeiture of any excess Incentive-Based Compensation received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare the accounting restatement (the "**Look-Back Period**"). For the purposes of this Policy, the date on which the Company is required to prepare an accounting restatement is the earlier of (i) the date the Board concludes or reasonably should have concluded that the Company is required to prepare a restatement to correct a material error, and (ii) the date a court, regulator, or other legally authorized body directs the Company to restate its previously issued financial statements to correct a material error. The Company's obligation to recover erroneously awarded compensation is not dependent on if or when the restated financial statements are filed.

Recovery of the Incentive-Based Compensation is only required when the excess award is received by a Covered Executive (i) after the beginning of their service as a Covered Executive, (ii) who served as an executive officer at any time during the performance period for that Incentive-Based Compensation, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Look-Back Period immediately preceding the date on which the Company is required to prepare an accounting restatement.

VI. Excess Incentive Compensation: Amount Subject to Recovery

The amount of Incentive-Based Compensation subject to recovery is the amount the Covered Executive received in excess of the amount of Incentive-Based Compensation that would have been paid to the Covered Executive had it been based on the restated financial statements, as determined by the Board. The amount subject to recovery will be calculated on a pre-tax basis.

For Incentive-Based Compensation received as cash awards, the erroneously awarded compensation is the difference between the amount of the cash award that was received (whether payable in a lump sum or over time) and the amount that should have been received applying the restated Financial Reporting Measure. For cash awards paid from bonus pools, the erroneously awarded Incentive-Based Compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

For Incentive-Based Compensation received as equity awards that are still held at the time of recovery, the amount subject to recovery is the number of shares or other equity awards received or vested in excess of the number that should have been received or vested applying the restated Financial Reporting Measure. If the equity award has been exercised, but the underlying shares have not been sold, the erroneously awarded compensation is the number of shares underlying the award.

In instances where the Company is not able to determine the amount of erroneously awarded Incentive-Based Compensation directly from the information in the accounting restatement, the amount will be based on the Company's reasonable estimate of the effect of the accounting restatement on the applicable measure. In such instances, the Company will maintain documentation of the determination of that reasonable estimate.

VII. Method of Recoupment

The Board will determine, in its sole discretion, subject to applicable law, the method for recouping Incentive-Based Compensation hereunder, which may include, without limitation:

- requiring reimbursement of cash Incentive-Based Compensation previously paid;

- seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
- cancelling outstanding vested or unvested equity awards; and/or
- taking any other remedial and recovery action permitted by law, as determined by the Board.

VIII. No Indemnification; Successors

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Incentive-Based Compensation. This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

IX. Exception to Enforcement

The Board shall recover any excess Incentive-Based Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with Rule 10D-1 of the Exchange Act and any applicable rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed.

X. Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC and any national securities exchange on which the Company's securities are listed.

XI. Effective Date

This Policy shall be effective as of November 9, 2023 (the "**Effective Date**") and shall apply to Incentive-Based Compensation that is received by a Covered Executive on or after that date, as determined by the Board in accordance with applicable rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed.

XII. Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to comply with any rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed. The Board may terminate this Policy at any time.

XIII. Other Recoupment Rights

Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.