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, 2024
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 001-42179

Artiva Biotherapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-3614316**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5505 Morehouse Drive, Suite 100 San Diego CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 267-4467

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	ARTV	The Nasdaq Global 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 Registrant did not have an aggregate market value for the common equity held by non-affiliates of the Registrant on the last business day of its most recently completed second fiscal quarter because there was no public market for the Registrant's common equity as of such date.

The number of shares of Registrant's Common Stock outstanding as of March 19, 2025 was 24,363,119.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2025 annual meeting of shareholders (the Proxy Statement) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

Artiva Biotherapeutics, Inc.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding future events, our business strategy, and the plans and objectives of management for future operations, are forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions.

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost, timing and potential indications of our product development activities and clinical trials, including the ongoing clinical trials of AlloNK;
- the timing of our planned Investigational New Drug application (IND) submissions to the United States Food and Drug Administration (FDA) for our product candidates, including AlloNK;
- the timing of the initiation, enrollment and completion of planned clinical trials;
- the ability to obtain regulatory approval for our manufacturing facility in San Diego, California and the cost and timing associated therewith;
- our ability to obtain and maintain regulatory approval of our product candidates, including AlloNK, in any of the indications for which we plan to develop them, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our product candidates, including AlloNK;
- our plans to research and develop our product candidates, including AlloNK;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates, including AlloNK;
- the rate and degree of market acceptance of our product candidates, including AlloNK;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or become available;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- the implementation of our business model and strategic plans for our business and operations;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

•our expectations regarding the impact of global health pandemics, geopolitical conflicts and economic uncertainty, including rising interest rates and inflation on our business and operations, including clinical trials, collaborators, contract research organizations (CROs) and employees;

•our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act); and

•our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in greater detail under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we undertake no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

We may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the U.S. Securities and Exchange Commission (SEC). These disclosures will be included on our website under the "Investors" section.

Risk Factor Summary

Below is a summary of the principal risks and uncertainties that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary, and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our securities. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

The following is a summary of the principal risks and uncertainties described in more detail in this Annual Report:

•We have a limited operating history, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

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

•Our approach to the development of NK cell-based product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.

•Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of developing product candidates and obtaining regulatory approval for any product candidates that we develop.

•We are early in our development efforts and are substantially dependent on the success of our lead product candidate, AlloNK, which is in early clinical development. Although we have other product candidates in our pipeline being developed by our partners, all of our other internally developed product candidates are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

•Current clinical data regarding the efficacy of NK cell therapies against autoimmune diseases are limited, raising uncertainties about the therapeutic benefits of treatments like AlloNK for conditions such as SLE, LN, RA, PV, GPA / MPA and other autoimmune diseases. Moreover, these therapies may not prove to be competitive compared to existing treatments for autoimmune diseases.

•Clinical trials are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

•Our product candidates may cause serious adverse events or undesirable side effects or have other properties that may delay or prevent regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

•Enrollment and retention of patients in clinical trials is an expensive and time-consuming process subject to various external factors beyond our control that may cause delays or complications.

•Results of any patient who receives our product candidate in an investigator initiated trial should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for regulatory approval.

•The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

•Our collaboration agreements with Affimed GmbH, a subsidiary of Affimed N.V. (Affimed), GC Cell Corporation (GC Cell) and any future collaborations with third parties to develop or commercialize our product candidates, mean that our prospects with respect to the product candidates involved will depend in significant part on the success of those collaborations.

•The manufacture of cell therapy products is novel, complex and subject to multiple risks. We could experience manufacturing problems, and/or we could be required to or choose to modify our manufacturing processes, which could result in delays in the development or commercialization of our product candidates or otherwise harm our business.

•We currently rely on GC Cell for the manufacturing of certain of our product candidates. While we have built our own clinical manufacturing facility and may decide to operate our manufacturing facility at commercial-scale, we may encounter delays, quality or other issues if and when we begin to use our manufacturing facility for supply, and will continue to rely on GC Cell at least partially for manufacturing of our product candidates in the near term.

•Our partial reliance on third parties for manufacturing increases the risk that supply of our product candidates may become limited or interrupted or may not be of satisfactory quality and quantity.

•We are dependent on third parties to acquire, ship and store our cord blood units, NK cell master cell banks and drug product lots, viral vectors, and master and working feeder cell banks, and any disruption, quality concerns, damage or loss would cause delays in replacement and our business could suffer.

•Our cell therapy products depend on the availability of reagents and specialized materials and equipment, including cord blood and viral vectors, which in each case are required to be acceptable to the FDA and comparable foreign regulatory authorities, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We and our third-party manufacturers rely on third-party suppliers for various components, materials and equipment required for the manufacture of our product candidates, some of which are single-source products, and do not have supply arrangements for certain of these components.

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

•We depend substantially on intellectual property rights granted under our agreements with GC Cell. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.

•We will need to expand our organization, and we may experience significant challenges in managing this growth as we build our capabilities, which could disrupt our operations.

•Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company focused on developing natural killer (NK) cell-based therapies for patients suffering from devastating autoimmune diseases and cancers. Our product candidates are derived from donor cells (allogeneic) rather than a patient's own cells (autologous) and are pre-manufactured, and stored frozen and ready to ship to a patient's treatment location, making them what we believe to be "off-the-shelf." Our lead product candidate, AlloNK, is a non-genetically modified, cryopreserved NK cell therapy being evaluated in combination with B-cell targeted monoclonal antibodies (mAbs) in an ongoing Phase 1/1b trial in SLE with or without lupus nephritis (LN) and a basket investigator-initiated trial (IIT) in multiple autoimmune indications. Seminal peer-reviewed clinical studies using autologous CD19 chimeric antigen receptor (CAR) T-cell therapy (auto-CAR-T) for the treatment of autoimmune diseases have demonstrated that deep B-cell depletion in the periphery and in the lymphoid tissue can lead to drug free disease remission. We have already demonstrated that AlloNK in combination with rituximab was able to drive deep B-cell depletion in the periphery and observed complete responses (CRs) in heavily pre-treated patients naïve to auto-CAR-T in our ongoing Phase 1/2 clinical trial in patients with relapsed or refractory B-cell-non-Hodgkin lymphoma (B-NHL). We believe the preliminary results from our Phase 1/2 clinical trial evaluating AlloNK in combination with rituximab in patients with B-NHL provide a readthrough to autoimmune disease because efficacy in both diseases appears to be accomplished with a shared mechanism of action involving B-cell depletion in the periphery and in the lymphoid tissues, followed by an immunological reset and B-cell reconstitution. We expect to report initial data on autoimmune indications from at least one of our Phase 1/1b trial or the basket IIT in the first half of 2025.

To our knowledge, AlloNK was the first allogeneic, off-the-shelf NK cell therapy candidate to receive Investigational New Drug application (IND) clearance to be administered to a patient with an autoimmune disease in a U.S. clinical trial, and to receive United States Food and Drug Administration (FDA) Fast Track designation in an autoimmune disease. Additionally, to our knowledge, AlloNK is the first allogeneic NK cell therapy candidate in the United States to receive IND clearance for a basket trial in autoimmune diseases, and specifically the first to be evaluated in rheumatoid arthritis (RA), pemphigus vulgaris (PV), and the anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis (AAV) subtypes granulomatosis with polyangiitis (GPA) / microscopic polyangiitis (MPA), which we are exploring through a basket IIT. We believe as we continue to execute on our strategic plan that these critical first mover advantages will solidify our leadership in multiple autoimmune diseases with high unmet need. Receiving IND clearance and any special designations, such as Fast Track designation, does not guarantee an accelerated review of AlloNK or increase the likelihood of approval of AlloNK by the FDA. Given our early stage of development, it will take several years before we complete clinical development and receive regulatory approval of AlloNK or any of our product candidates, if at all.

B-Cell Driven Autoimmune Disease Background, Prevalence and Unmet Need

Many autoimmune diseases occur when autoreactive B-cells produce autoantibodies that target the body's own healthy cells and tissues, which can lead to significant morbidity and long-term steroid use. This presents an opportunity to develop treatments that deplete B-cells in a variety of autoimmune diseases such as RA, multiple sclerosis (MS), systemic lupus erythematosus (SLE), LN, AAV, systemic sclerosis (SSc), myasthenia gravis (MG), and myositis, which together account for approximately 6.8 million patients in the United States and Europe alone. Global sales for autoimmune disease, treatments for which in 2023 reached approximately $160 billion (including $65 billion for the top ten immunology and inflammation drugs focused on rheumatology) and represent the second-largest class of spending behind oncology, are expected to continue to grow.

Approved treatments for autoimmune diseases encompass various classes of therapies, including steroids, mycophenolate mofetil (MMF), anti-tumor necrosis factor alpha (TNFα) agents and interleukin (IL) inhibitors. Even though these therapies largely provide general immunosuppression and manage symptoms of disease, many patients still suffer from disease progression, leading to worsening complications. Furthermore, chronic use of these therapies typically creates secondary complications for patients, including, but not limited to, increased risk of infections and cancer, cardiovascular disease, hypertension, Cushing's disease, diabetes and osteoporosis.

While auto-CAR-T cell therapies have demonstrated the transformative potential of cell therapy, adoption has been limited since their initial approvals due to several factors, including but not limited, to safety, patient access, and scalability. We believe AlloNK in combination with B-cell targeted mAbs represents the next-generation of B-cell depleting therapies because it aims to address important limitations of auto-CAR-T, including:

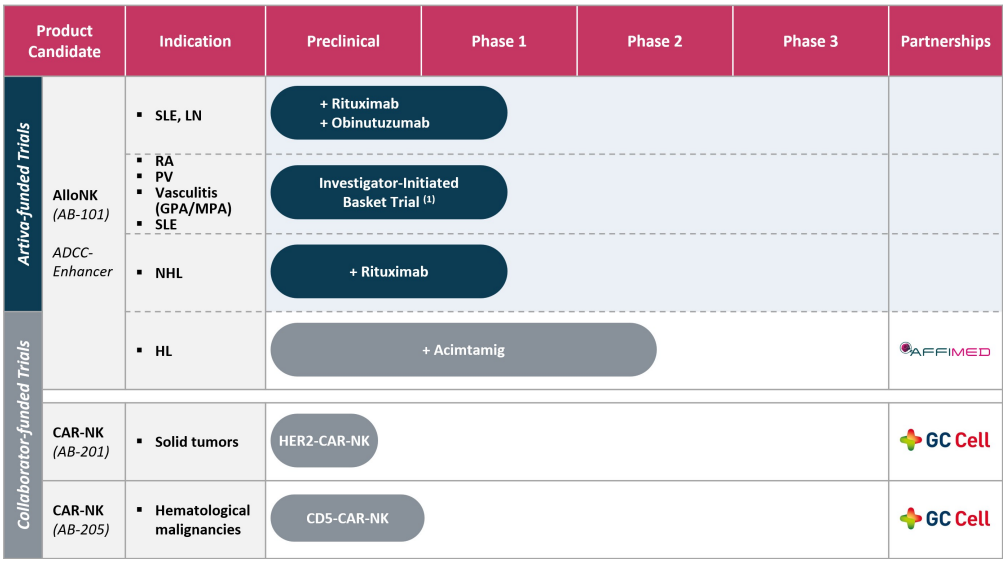
- *Scalability:* AlloNK can be manufactured at scale, cryopreserved, easily transported through cold-chain logistics, and we believe be made readily available for patients. In contrast, auto-CAR-T requires a complex, costly, and lengthy manufacturing process that is individualized for each patient. The need for hospitalization further compounds the challenges of scalability and access, adding financial burden to the healthcare system. For example, toxicity and extended hospitalization from treatment with auto-CAR-T could add an incremental financial burden of over $1 million per patient. The scalability of our process creates the potential to expand treatment access to the many autoimmune patients annually who currently live with the consequences of long-term steroid use.

- *Safety:* As a result of autologous and allogeneic CAR-T cell therapies' association with immune effector cell-associated neurotoxicity syndrome (ICANS), cytokine release syndrome (CRS) and other severe adverse events, treatment is generally only available at advanced clinical centers capable of supporting these patients. Conversely, in our clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL, as of April 8, 2024, more than two thirds of the patients were not hospitalized within 30 days of dosing AlloNK. We believe this demonstrates, the ability of AlloNK to be administered and managed in an outpatient setting, with limited risk of required hospitalization.

- *Cost:* Cost of goods sold (COGS) to manufacture auto-CAR-Ts is estimated at over $100,000 per treatment course, limiting flexibility in therapy pricing. Assuming a range of one billion to four billion AlloNK cells per dose and three doses for a treatment regimen of an aggregate of three billion to twelve billion AlloNK cells total per patient with autoimmune disease, AlloNK's COGS per patient would be below a range of $3,000 to $12,000, approximately an order of magnitude below the current COGS of auto-CAR-T. As auto-CAR-Ts move from their currently marketed indication of hematological malignancies towards chronic and more prevalent autoimmune diseases, AlloNK's extremely competitive commercial COGS could allow for advantageous pricing flexibility and payor coverage, if approved.

Our Pipeline

Our lead product candidate, AlloNK, is currently being evaluated in combination with B-cell targeted mAbs in patients with autoimmune diseases and cancers, such as SLE, LN, RA, PV, the ANCA-associated vasculitis subtypes GPA / MPA and B-NHL. In addition, we are also pursuing AlloNK and our CAR-NK product candidates in multiple indications through collaborator-funded trials. Our current pipeline is depicted below.



Note: Artiva holds ex-APAC rights to all programs.

(1)The IIT will initially enroll patients with RA, PV, GPA / MPA, and SLE.

AlloNK Overview

AlloNK is an allogeneic, off-the-shelf, cryopreserved NK cell therapy candidate designed to enhance the antibody-dependent cellular cytotoxicity (ADCC) effect of mAbs to drive B-cell depletion and to be administered in the community setting. Using our proprietary cell therapy manufacturing platform, we can generate thousands of doses of cryopreserved, infusion-ready AlloNK from a single cord blood unit.

Our lead product candidate, AlloNK, is being evaluated in combination with B-cell targeted mAbs in an ongoing Phase 1/1b trial in patients with SLE with or without LN, a type of kidney disease that manifests from SLE, and a basket IIT in multiple autoimmune indications. LN is reported to affect approximately half of all patients with SLE. There are an estimated 210,000 SLE patients with LN across the United States and Europe, and approximately 30% do not respond to currently available treatments and can develop end stage renal disease and require dialysis.

We have begun dosing and are continuing to enroll our Phase 1/1b open-label multi-center clinical trial in combination with rituximab or obinutuzumab in patients with SLE with or without LN who previously failed treatment. In addition, AlloNK in combination with rituximab or obinutuzumab has been granted Fast Track designation by the FDA to improve disease activity in patients with class III or class IV LN. We also received Fast Track designation for AlloNK for intravenous (IV) infusion in combination with rituximab for the treatment of relapsed or refractory B-NHL to improve cancer response rates. Fast Track designation does not guarantee an accelerated review of AlloNK or increase the likelihood that AlloNK will receive regulatory approval by the FDA.

In April 2024, the FDA cleared an IND submitted by Integral Rheumatology & Immunology Specialists (IRIS), a large community practice rheumatology clinic in Florida, to conduct a basket IIT to assess the safety, tolerability and clinical activity of AlloNK in combination with rituximab in patients with RA, PV, the ANCA-associated vasculitis subtypes GPA / MPA and SLE. We supply AlloNK and funding for the IIT, but unlike our sponsored clinical trials, IRIS is the regulatory sponsor of, and responsible for, the conduct of the IIT. Treatment of the first patient in the basket IIT was initiated in August 2024.

We intend to pursue additional autoimmune diseases with AlloNK in combination with B-cell targeted mAbs.

Because AlloNK can be used with mAbs that target different antigens based on the target cell's antigen expression, we believe we have the versatility to use AlloNK in combination with different mAbs to deplete distinct B-cell subpopulations. AlloNK has the potential to be used with a CD19 or CD20 targeting mAb to determine which drives a more robust response. Furthermore, emerging evidence with auto-CAR-T targeting B-cell maturation antigen (BCMA), a plasma cell antigen, either alone or dual-targeted with CD19, has shown distinct therapeutic activity in several indications when compared with CD19-only auto-CAR-T. We believe AlloNK in combination with approved anti-CD38 mAbs could target a similar plasma cell population. We believe this versatility will enable us to pursue a wider range of indications than cell therapies engineered against specific targets.

Our Collaborator-Funded Trials

We have a collaboration with Affimed, whereby we are investigating AlloNK in a Phase 2 trial in combination with acimtamig, a CD30-targeted NK cell engager, in CD30+ Hodgkin lymphoma (HL). In addition, we own exclusive worldwide rights (excluding Asia, Australia and New Zealand (ex-APAC)) for AB-201, a human epidermal growth factor receptor 2 (HER2) targeting CAR-NK cell product candidate, and for AB-205, a CD5 directed CAR-NK cell product candidate.

Manufacturing Capabilities

We have a manufacturing-first approach, referencing the fact that even before we were founded, our strategic partner, GC Cell, had already invested years pioneering the manufacturing process that we use today. Unlike most other companies in the NK field who started clinical development before establishing a scalable manufacturing process, we started clinical development with a mature and robust process in place. Our process is designed to allow us to produce off-the-shelf, allogeneic NK cell therapy candidates and to potentially meet the scale of commercial demand, with the mission to make these therapies broadly accessible for patients with devastating autoimmune diseases and cancers. We leveraged our deep expertise in NK cell biology to establish an end-to-end proprietary process in collaboration with GC Cell. In our San Diego headquarters, we have established a 9,000 square foot, purpose-built cell production center that is compliant with current Good Manufacturing Practices (cGMP) and capable of producing enough vials to treat over 250 to 1,000 autoimmunity patients annually, depending on the cells per dose used. Furthermore, assuming a range of one billion to four billion AlloNK cells per dose and three doses for a treatment regimen of an aggregate of three billion to twelve billion AlloNK cells total per patient with autoimmune disease, AlloNK COGS per patient would be below a range of $3,000 to $12,000, approximately an order of magnitude below the current COGS of auto-CAR-T.

Our Management Team, History and Investors

We were founded in 2019 as a spin out of GC Cell, formerly GC Lab Cell Corporation, a leading healthcare company in the Republic of Korea (Korea), pursuant to a strategic partnership granting us exclusive, worldwide, ex-APAC, rights to GC Cell's NK cell manufacturing technology and programs. GC Cell has an established track record in cell therapy, with over two decades of cell therapy research, process development and manufacturing experience, as well as a clinical and commercial track-record outside the United States with the first ever marketed T-cell product, Immuncell-LC, which received South Korean Ministry of Food and Drug Safety (MFDS) approval for hepatocellular carcinoma in 2017. An investigational version of the product candidate also received FDA Orphan Drug Designation for pancreatic cancer, liver cancer and glioblastoma in 2018. In addition, GC Cell spent over a decade optimizing the manufacturing process for NK cell therapeutics, including selection of cord blood as a starting material, expanding process scale and enabling cryopreservation. GC Cell utilizes a custom-built

300,000 square foot cell therapy research, process development and cGMP manufacturing facility from which we were able to produce drug product for our first clinical trials in the United States.

Our team is led by executives who have deep experience in their respective functions in cell therapy with multi-faceted experience across a company's life cycle. Our leadership team has extensive combined experience in therapeutics, medical devices and diagnostics companies. We have also assembled scientific advisors with deep experience in both cell therapy and autoimmune disease who are actively involved in our drug development process and programs.

Our Mission

Our mission is to develop effective, safe and accessible cell therapies for patients with devastating autoimmune diseases and cancers.

Our Strengths

We believe that our company and therapeutic candidates possess the following competitive strengths.

▪**Autoimmune disease treatment approach supported through scientific publications and our ongoing clinical trial.** Our conviction in the transferability of our proposed mechanism of action from treatment of B-NHL to treatment of autoimmune diseases is driven by both the peer reviewed scientific publication of clinical trial results of auto-CAR-T in autoimmune diseases as well as preliminary data from our ongoing Phase 1/2 clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL. In all 29 patients in our trial with samples analyzed, as of March 26, 2024, following the first cycle of treatment, all patients achieved non-quantifiable peripheral B-cell levels by Day 8 (except for one patient who achieved such B-cell depletion by Day 15) following the start of therapy, regardless of B-cell levels at baseline. We believe this data provides support for a B-cell depleting mechanism of action of AlloNK in combination with B-cell targeted mAbs. AlloNK in combination with rituximab has also demonstrated CRs in B-NHL patients as measured by imaging of tumor lesions. Because of the common tissues of interest, principally the lymphoid tissues, in B-NHL and autoimmune diseases, we believe data in these B-NHL patients provides supporting evidence for our proposed mechanism of action in autoimmune disease. In the Phase 1 portion of this trial, as of April 30, 2024, in the fourteen patients who were naïve to CAR-T, the overall response rate (ORR), which is the proportion of patients who have a partial response (PR) or CR, was 71%, including eight CRs (57%), and two PRs (14%), as determined by the Lugano 2014 criteria. The Lugano 2014 criteria is a widely accepted and published methodology used in clinical trials as well as in clinical practice for response assessment in lymphoma. The criteria recommend a combination of disease morphology assessment using computed tomography (CT) and lesion metabolic activity assessment on positron emission tomography (PET), with PET metabolic assessments being the driver for overall response assessment. For further description of the 2014 Lugano criteria, please see pages 131-132. Thirteen of these patients had aggressive forms of B-NHL, and the CR rate in this subset, as determined by the Lugano 2014 criteria, was 62%. As of the April 30, 2024, data cutoff date, six of the eight patients with a CR had an ongoing response (meaning continuation of the CR at all follow-up points), with five of these patients remaining progression free at six months or later. The longest responder remained progression free for at least 18 months after the start of treatment. We believe these data support that AlloNK in combination with B-cell targeted mAbs has the potential to provide deep B-cell depletion in common target tissues between B-NHL and autoimmune diseases and offer therapeutic potential, a differentiated safety profile and patient accessibility in numerous autoimmune diseases.

▪**Versatile mAb combination approach allows flexibility to tailor targeting approach to specific B-cell subpopulations.** We believe combining AlloNK with approved B-cell targeted mAbs may offer therapeutic benefits in a broad range of B-cell-driven diseases. AlloNK, as a non-genetically modified, non-targeted NK cell, is designed to utilize a mAb for targeting. Therefore, we believe different mAbs could be used to target distinct B-cell populations based on the target cell's antigen expression. Beyond rituximab and other anti-CD20 mAbs, we have already conducted numerous preclinical studies in which we have shown cytotoxic activity of AlloNK in combination with other approved B-cell targeted mAbs, such as anti-CD19 and anti-CD38 mAbs. Emerging evidence

with auto-CAR-T targeting the plasma cell antigen BCMA, either alone or dual-targeted against CD19, has shown distinct therapeutic activity in several indications when compared with CD19-only auto-CAR-T, and we believe AlloNK in combination with approved anti-CD38 mAbs could target a similar plasma cell population. We have the opportunity to develop AlloNK in combination with approved B-cell targeted mAbs using a variety of targets, including the potential for dual targeting by treating in combination with two mAbs. We believe this versatility will enable us to pursue a wider range of indications than cell therapies engineered against specific targets.

▪**Proprietary manufacturing process allows for scalable and potentially cost effective AlloNK production.** Our robust chemistry, manufacturing and controls (CMC) experience, ample capacity and limited overhead enable us to produce allogeneic, off-the-shelf, NK cell therapy candidates at scale. Utilizing our proprietary process we and GC Cell have manufactured over 50 clinical batches of AlloNK, producing thousands of AlloNK vials at one billion cells per vial, and have demonstrated both batch-to-batch and donor-to-donor consistency. Our manufacturing platform and scale-up process is rooted in over a decade of NK cell expansion experience by our strategic partner, GC Cell, and has been further improved upon by our team. In our San Diego headquarters, we have established a 9,000 square foot, purpose-built cell production center that is cGMP-compliant, and capable of producing enough vials to treat over 250 to 1,000 autoimmunity patients annually, depending on the cells per dose used. We are developing a 200-liter, commercial-scale process that we believe has the potential to efficiently supply many thousands of patients with a COGS below $1,000 per one billion-cell vial. Furthermore, assuming a range of one billion to four billion AlloNK cells per dose and three doses for a treatment regimen of an aggregate of three billion to twelve billion AlloNK cells total per patient with autoimmune disease, AlloNK COGS per patient would be below a range of $3,000 to $12,000, approximately an order of magnitude below the current COGS of auto-CAR-T. With this COGS, we could have the flexibility to reduce the price relative to auto-CAR-T while still maintaining a high margin.

▪**Non-genetically modified cell therapy has not shown integrating vector-induced secondary malignancies, which is a benefit in an autoimmunity setting.** As of December 31, 2023, the FDA had received reports of 22 cases of secondary T-cell malignancies (including CAR+ lymphoma) in patients who received treatment with BCMA- or CD19-directed genetically modified auto-CAR-T therapy. Transgene insertion of CAR was detected in the malignant clone in each of the three cases for which genetic sequencing was performed. As a result, in January 2024, the FDA determined that boxed warning language addressing these malignancies should be included on the label for all BCMA- and CD19-directed genetically modified auto-CAR-Ts to alert patients and clinicians of the potential risk of developing secondary T-cell malignancies following treatment. Unlike CAR-T and any genetically modified cell therapy, AlloNK is a non-genetically modified NK cell therapy candidate and has not shown any secondary malignancies in our clinical trials as of April 8, 2024. We believe this will make our therapeutic candidate a preferable and differentiated treatment option for physicians and patients.

▪**AlloNK cell approach aims to broaden community access, drive improved patient experience, improve clinical recruitment timelines and expand commercial opportunity**. In our clinical trials to date, AlloNK in combination with a B-cell targeted mAb was mostly administered and managed outside of a hospital setting. This is in contrast to auto-CAR-T cell therapies, which have been limited by the need for hospitalization due to the risks of ICANS and CRS, among other severe adverse events. Our product candidate is designed to enable rheumatologists to administer AlloNK in combination with a B-cell targeted mAb within their own outpatient infusion centers, potentially allowing patients to avoid the typically required hospitalization associated with CAR-T cell therapies. These limitations are also present for T-cell engaging bispecific antibodies. Approved T-cell engaging bispecific antibodies such as glofitamab, epcoritamab, and mosunetuzumab require hospitalization upon dosing due to the risk of CRS. We believe the potential to administer an off-the-shelf therapy in an outpatient setting could meaningfully reduce the patient's treatment burden, translating to a potential competitive advantage in enrolling patients in our clinical trials and capturing market share, if approved.

▪**Strategic execution led to first-mover advantage in autoimmune disease.** We have advanced AlloNK into clinical trials for autoimmune diseases, and we believe we have achieved multiple critical clinical and regulatory milestones ahead of other allogeneic, off-the-shelf NK cell therapy companies. Specifically, the FDA cleared our IND for AlloNK in combination with rituximab for our Phase 1/1b

clinical trial in patients with class III or IV LN in August 2023, and we dosed the first patient in this trial in April 2024. We also amended the ongoing trial to broaden the patient population to include patients with SLE without LN. To our knowledge, this made AlloNK the first allogeneic, off-the-shelf NK cell therapy candidate to be administered to a patient with an autoimmune disease in a U.S. clinical trial and the first allogeneic, off-the-shelf NK cell therapy to receive Fast Track designation in an autoimmune indication. Further, in April 2024, the FDA cleared an IND submitted by IRIS, a large community practice rheumatology clinic in Florida, to conduct a basket IIT in multiple autoimmune indications. Treatment of the first patient in this basket IIT was initiated in August 2024. Through this IIT, to our knowledge, AlloNK is the first allogeneic NK cell therapy candidate in the United States to receive allowance to proceed with a basket study under an IND, and specifically the first to be evaluated in RA, PV and AAV, which we believe solidifies our potential leadership in multiple large-market diseases. We believe our established manufacturing capabilities empower us to capitalize on our first-mover advantage to efficiently develop and, if approved, potentially commercialize a wide range of indications relative to auto-CAR-Ts, which we believe are constrained due to the limitations associated with manufacturing autologous cell therapies. We believe all of these potential advantages, along with our expected competitive advantage in enrollment timing, will allow us to efficiently progress AlloNK through the clinic and position us to capitalize on the broad market opportunity of B-cell driven autoimmune diseases. Receiving IND clearance and any special designations, such as Fast Track designation, does not guarantee an accelerated review of AlloNK or increase the likelihood of approval of AlloNK by the FDA. Given our early stage of development, it will take several years before we complete clinical development and receive regulatory approval of AlloNK or any of our product candidates, if at all.

▪**Leading scientific advisors who guide our development strategy in autoimmune disease.** With our focus on developing AlloNK in autoimmune diseases, we have rapidly assembled key opinion leaders from leading academic and medical institutions including UC San Diego, UCLA, NYU and OSU to serve as advisors and guide our development.

Our Strategy

Our strategy is to develop safe and effective NK cell-based therapies that patients and physicians can utilize in a community setting. We believe the compelling cell killing properties of NK cells, when combined with mAbs for targeting specific antigens, creates an opportunity to generate potentially transformative therapies. Key elements of our strategy include:

▪**Advance our lead product candidate, AlloNK, through clinical development and demonstrate the clinical potential of NK cell therapies in autoimmune diseases.** We are advancing AlloNK through clinical development to address the significant unmet need in autoimmunity as well as patient and physician desire for a safe, accessible therapy. We believe data from our Phase 1/2 clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL support the potential for AlloNK in combination with B-cell targeted mAbs to provide deep B-cell depletion in common target tissues between B-NHL and autoimmune diseases. The FDA cleared our IND for AlloNK in combination with rituximab for our Phase 1/1b clinical trial in patients with class III or class IV LN in August 2023, and we dosed the first patient in this trial in April 2024. We also amended the protocol for this trial to broaden the patient population to include patients with SLE without LN.

▪**Demonstrate the clinical potential of NK cell therapies to address limitations of auto-CAR-Ts.** Auto-CAR-Ts have proven to be an effective therapeutic modality in cancer and have shown therapeutic clinical benefit in autoimmune disease. We believe this is the first step in an evolution where next generations of the technology will improve safety and expand access to the point where cell therapies truly are available to any patient in need. We have optimized an end-to-end NK cell manufacturing process to potentially deliver AlloNK on a large scale and at low cost, having leveraged more than a decade of NK cell manufacturing expertise and know-how. We believe AlloNK in combination with B-cell targeted mAbs represents the next-generation of B-cell depleting therapies because it aims to address important limitations of auto-CAR-T, including:

▪*Scalability:* AlloNK is an allogeneic, off-the-shelf product candidate that can be manufactured at scale, cryopreserved, easily transported through cold-chain logistics and we believe can be made

readily available for patients. In contrast, auto-CAR-T therapy requires a complex, costly, and lengthy manufacturing process that is individualized for each patient. The need for hospitalization further compounds the challenges of scalability and access, adding financial burden to the healthcare system. For example, toxicity and extended hospitalization from treatment with auto-CAR-T could add an incremental financial burden. According to a real-world study conducted in 2021 by Oregon Health & Science University and presented by Maziarz *et al*. the average cost of treatment, excluding the cost of auto-CAR-T itself, was $383,000 and could reach over $1 million per patient. The scalability of our process creates the potential to expand treatment access to the many autoimmune patients annually who currently live with the consequences of long-term steroid use.

- *Safety:* As a result of autologous and allogeneic CAR-Ts' association with CRS, ICANS, and other severe adverse events, treatment is generally only available at advanced clinical centers capable of supporting these patients. Conversely, in our clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL, as of April 8, 2024, more than two-thirds of the patients were not hospitalized at all within 30 days of dosing AlloNK. We believe this demonstrates the ability of AlloNK to be administered and managed in an outpatient setting, with limited risk of required hospitalization.

- *Cost:* Cost of goods to manufacture auto-CAR-Ts is estimated at over $100,000 per treatment course, limiting flexibility in therapy pricing. Assuming a range of one billion to four billion AlloNK cells per dose and three doses for a treatment regimen of an aggregate of three billion to twelve billion AlloNK cells total per patient with autoimmune disease, AlloNK COGS per patient would be below a range of $3,000 to $12,000, approximately an order of magnitude below the current COGS of auto-CAR-T. As auto-CAR-Ts move from their currently marketed indication of hematological malignancies towards chronic and more prevalent autoimmune diseases, AlloNK's extremely competitive commercial COGS could allow for advantageous pricing flexibility and payor coverage, if approved.

- **Expand AlloNK development across several autoimmune indications utilizing different mAbs.** We are further exploring the potential of AlloNK in other indications and other antibody combinations through IITs and company-sponsored clinical trials. In April 2024, the FDA cleared an IND submitted by IRIS, a large community practice rheumatology clinic in Florida, to conduct a basket IIT under an IND testing the combination of AlloNK with rituximab in a study of four autoimmune diseases: RA; PV; GPA / MPA; and SLE.

- **Continue to evaluate and pursue tailored strategies to advance our platform capabilities and maximize patient access to AlloNK.** We have a disciplined strategy to evaluate partnerships that are designed to further our NK cell development and manufacturing efforts with the goal of delivering our product candidates to as many patients as stand to benefit. Our two main manufacturing and oncology program development partnerships with GC Cell and Affimed, respectively, are products of this strategy. We also plan to commercialize our product candidates and will look to make further investments at the appropriate time to maximize access and the commercial potential of our product candidates.

Introduction to Autoimmune Disease

Background

Many autoimmune diseases occur when autoreactive B-cells produce autoantibodies that target the body's own healthy cells and tissues instead of foreign pathogens. In a healthy individual, these malfunctioning immune cells, such as B-cells and T-cells, are either eliminated before they fully develop or are kept in check by various regulatory mechanisms. However, in individuals with autoimmune diseases, these safety measures are compromised due to a mix of genetic factors and exposure to certain antigens from infections or environmental sources.

The prevalence of autoimmune diseases is both widespread and growing, with over 80 known autoimmune diseases. The persistent and severe nature of these diseases results in substantial medical expenses and a decline in quality of life, posing significant challenge for patients, their families and the healthcare system. Global sales for

autoimmune disease, treatments for which in 2023 reached approximately $160.0 billion (including $65 billion for the top ten immunology and inflammation drugs focused on rheumatology) and represent the second-largest class of spending behind oncology, are expected to continue to grow. There is a significant unmet medical need in autoimmune diseases despite the number of approved therapies, given these treatments are often not curative and many patients do not achieve optimal outcomes.

B-Cell Driven Autoimmune Diseases

Autoimmune diseases encompass a broad range of diseases and symptoms, with the presence of autoantibodies—produced by autoreactive B-cells that mistakenly target the body's healthy cells and tissues—being a common characteristic of many autoimmune diseases. While the specific autoantigen targeted and the primary affected tissue or organ may vary, the role of B-cells in producing these autoantibodies is generally consistent. Increasing evidence suggests that autoreactive B-cells also contribute to the pathology of many autoimmune diseases through their interaction with T-cells and cytokine production. This shared biological mechanism presents an opportunity to develop treatments targeting the production of autoantibodies by B-cells for a variety of autoimmune diseases.

The following table sets forth the estimated prevalence for select B-cell-driven autoimmune diseases in the United States and in Europe.

	United States	Europe	Combined
Rheumatoid Arthritis	**1.3M**	**2.3M**	**3.6M**
Multiple Sclerosis	**750K**	**1.2M$^{\delta}$**	**2.0M**
ANCA Vasculitis	**100K**	**205K**	**305K**
Systemic Sclerosis *(Scleroderma)*	**85K**	**130K**	**215K**
Systemic Lupus Erythematosus *(Non-Lupus Nephritis)*	**100K**	**115K$^{\delta}$**	**215K**
Lupus Nephritis	**100K**	**110K**	**210K**
Myasthenia Gravis	**60K**	**90K**	**150K**
Myositis	**45K**	**100K**	**145K**
Total			**~6.8M**

All figures for Europe are for geographic Europe, except δ: which is for the European Union.

Limitations of Current Therapies

Approved treatments for autoimmune diseases encompass various classes of therapies, including steroids, MMF, TNFα agents and IL inhibitors. These therapies largely provide general immunosuppression and manage symptoms of disease. For instance, steroids and MMF have broad anti-inflammatory and immune-suppressing effects, anti-TNFα therapies inhibit TNFα, a cytokine involved in systemic inflammation, and IL inhibitors target certain ILs that activate the immune system and cause inflammation, such as IL-1 and IL-6. Even though these therapies largely provide general immunosuppression and manage symptoms of disease, many patients suffer from disease progression, leading to worsening complications. Furthermore, chronic use of these therapies typically creates secondary complications for patients, including, but not limited to, increased risk of infections and cancer, cardiovascular disease, hypertension, Cushing's disease, diabetes and osteoporosis. Monoclonal antibodies that

target B-cell antigens have also received approval for treating various diseases involving pathological B-cells, including autoimmune diseases and blood cancers. Rituximab, a mAb targeting the B-cell antigen CD20, has demonstrated effectiveness in treating several autoimmune diseases, including RA, PV and AAV. However, rituximab alone does not typically induce complete B-cell depletion in all patients, which may account for incomplete and inconsistent clinical responses. For instance, a pivotal Phase 3 trial of rituximab for the treatment of LN failed to show statistical improvement in clinical outcomes with rituximab when added to the standard of care, MMF and steroids, as compared to MMF and steroids alone. However, in a post-hoc analysis of the same trial data, it was observed that achievement of complete peripheral B-cell depletion, as well as the rapidity and duration of complete peripheral depletion, were associated with complete renal responses. We believe these data support the notion that if a therapy induces deeper and more consistent B-cell depletion, it will achieve higher response rates.

Promise of Cell Therapy in Autoimmune Disease

The advancement of auto-CAR-T cell therapies in oncology has opened the door to applying B-cell targeting cellular therapies in B-cell driven autoimmune diseases. Auto-CAR-T cell therapy involves genetically modifying a patient's own T-cells to produce and express a CAR, enabling the engineered T-cell to recognize and attack cancer cells more effectively. This personalized approach involves collecting the patient's T-cells, genetically engineering them in a laboratory to target a specific cancer cell antigen, then re-infusing these enhanced cells back into the patient to seek out and destroy cancer cells. Since the first auto-CAR-T cell therapy, Kymriah, was approved by the FDA in 2017 for the treatment of B-cell acute lymphoblastic leukemia (B-ALL), additional auto-CAR-Ts have been approved and uses have expanded to treatment of other forms of cancer, including certain types of NHL and multiple myeloma.

Auto-CAR-T products targeting CD19 have been transformative in the treatment of B-cell driven hematological malignancies such as B-ALL and NHL. The first FDA-approved auto-CAR-T cell therapies were designed to target CD19, a B-cell specific antigen prevalent in B-cell malignancies. The use of auto-CAR-T cell therapy aims to deplete these malignant cells as well as other CD19-expressing cells, including healthy B-cells. The ultimate aim of CD19 auto-CAR-T is to deplete cancerous B-cells in the periphery and lymphatic tissue where cancerous lesions grow, and CRs, measured by PET imaging coupled with computed tomography (CT) imaging (PET/CT) provide evidence that auto-CAR-T can target and deeply deplete these cancerous B-cells. Given the significance of B-cells in multiple autoimmune diseases, we believe the depletion of these cells will have a therapeutic benefit in a wide range of B-cell driven autoimmune diseases.

Cell Therapy in Autoimmune Disease with Auto-CAR-T Cell Therapy

The success of auto-CAR-T cell therapies in treating B-cell hematologic malignancies has spurred interest in applying these mechanisms for the treatment of various autoimmune diseases. Given the role of autoantibodies produced by autoreactive B-cells, as well as evidence suggesting that autoreactive B-cells contribute to the pathology of many autoimmune diseases through their interaction with T-cells and cytokine production, the hypothesis is that deeply depleting B-cells with targeted cell therapy will lead to clinical responses in autoimmune diseases.

Third-party clinical studies have shown that treating autoimmune disease with B-cell targeted cell therapy in patients who were refractory to other therapies resulted in rapid responses and remissions as determined by the Definition of Remission in SLE criteria, with patients not receiving further immunosuppressive drugs or steroids (drug-free remission). In 2022, a study led by Dr. Georg Schett reported results from five SLE patients treated with a CD19 auto-CAR-T, published in 2022 by Mackensen *et al*. in *Nature Medicine*. We believe several important observations from this provided insight into the potential value of B-cell targeted cell therapy.

- **Immune system reset**. Auto-CAR-T cells were observed to expand in vivo following treatment, and B-cells were rapidly and deeply depleted upon initiation of treatment. However, auto-CAR-T cells were short-lived in circulation, and all five patients experienced B-cell reconstitution after an average time of 110 days with no relapse of SLE.
- **Resolution of proteinuria**. Rapid reduction in proteinuria in the four patients with underlying LN, from urine protein creatinine ratio (UPCR) levels of 2-8 g/g Cr to <0.5g/g by three months.

▪**Elimination of autoantibodies**. Autoantibodies against common antigens in SLE, such as dsDNA, disappeared from the five patients, as well as autoantibodies against other antigens.

▪**Preservation of vaccination responses**. No substantial decline in immune responses against common vaccines, including measles, rubella, mumps, varicella zoster, hepatitis B, tetanus, diphtheria and pneumococci, were detected compared to baseline.

In a follow-up study published in *The New England Journal of Medicine* by Muller *et al*. in 2024, reporting data from the five patients above and three additional SLE patients, long-term follow-up of up to 29 months showed that disease activity remained absent in all eight SLE patients. The therapy was also observed to be effective in idiopathic inflammatory myositis, where all three patients treated had an American College of Rheumatology–European League against Rheumatism major clinical response and normalization of creatine kinase levels after three months and maintained these responses for up to 12 months; and in systemic sclerosis, where all four patients treated showed reduced severity of skin and lung disease for up to three months (and for up to six months in three patients that continued follow-up).

Limitations of Autologous CAR-T Cell Therapy

While auto-CAR-T cell therapies have demonstrated the transformative potential of cell therapy, adoption has been limited since initial approvals due to several factors, including, but not limited, to safety, patient access and scalability, as summarized below.

Safety

▪**Adverse Events:** Auto-CAR-T cell therapies have been associated with CRS and ICANS that could develop over a period of weeks. CRS in particular requires close observation, and any Grade 2 or higher case requires hospitalization and administration of tocilizumab. Auto-CAR-T products approved for use in NHL have shown that between 46% to over 90% of patients experience any grade CRS, with 4% to 13% experiencing serious Grade 3 or higher events. In practice, tocilizumab is often being utilized with Grade 1 CRS as well, possibly limiting the number of patients who escalate to Grade 2 and higher. For example, in a study by Schett of CD19 auto-CAR-T in autoimmune disease, 11 of 15 patients experienced CRS of any grade. Ten patients had Grade 1 CRS only, but tocilizumab was used in five of these patients. This early intervention and unpredictable time to onset requires that the patient remain within close proximity of a treatment facility that can manage CRS for a period of several weeks following the initial CAR-T infusion.

▪**Secondary T-Cell Malignancies:** Cells that have been genetically modified could have the potential to become cancerous, resulting in secondary T-cell malignancies. As with all gene therapy products with integrating vectors (lentiviral or retroviral vectors), the potential risk of developing secondary malignancies is labeled as a class warning in the United States prescribing information for approved BCMA-directed and CD19-directed genetically modified auto-CAR-T cell therapies. In January 2024, the FDA recommended updated safety language be added across product labels for all CD19 and BCMA auto-CAR-T cell therapies to highlight the risk of secondary T-cell malignancy, including language in the box warning.

Patient Access

▪**Limited Availability:** Treatment with auto-CAR-T cell therapies is generally only available at advanced clinical centers that can adequately support the complex logistics involved in the providing auto-CAR-T cell therapies and the patients that require extensive safety monitoring and potential need for hospitalization.

▪**High Cost Burden:** COGS to manufacture auto-CAR-T cell therapies is estimated at over $100,000 per treatment course. This may limit pricing flexibility and could constrain the number of patients able to afford treatment.

Manufacturing

- **Complex Manufacturing:** Because auto-CAR-T cell therapies are derived from a patient's own cells, they are subject to numerous potential inefficiencies inherent to a patient-specific manufacturing process. Manufacturing auto-CAR-T cell therapies is an intricate process that begins with leukapheresis to obtain T-cells from the patient's peripheral blood. These isolated T-cells are then shipped to a manufacturing site where CAR vectors are transduced and cells are expanded before being packaged as a drug product and returned to the clinical site for treatment. As many as 10% to 20% of patients may ultimately not receive product for treatment because of issues with either leukapheresis or the manufacturing process.

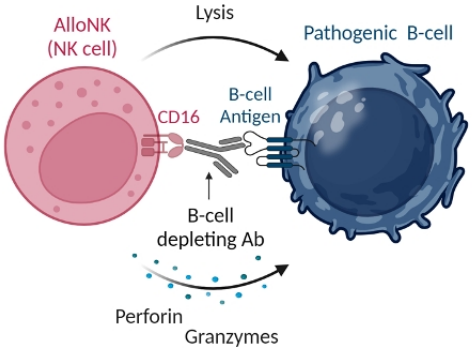
- **Lengthy Lead Time:** Because of such complexities, manufacturing processes for currently approved CAR-T cell therapies can take approximately three to five weeks following apheresis to be treated with their personalized auto-CAR-T cells.

Our Solution – AlloNK

AlloNK is an allogeneic, off-the-shelf, cryopreserved NK cell therapy candidate designed to enhance the ADCC effect of mAbs to drive B-cell depletion. In preliminary results from 29 B-NHL patients, as of March 26, 2024, AlloNK in combination with a B-cell targeted mAb has demonstrated deep depletion of peripheral B-cells and CRs in certain patients in clinical trials. Because in both B-NHL and autoimmune disease the potential therapeutic activity may be driven by B-cell depletion in the periphery and lymphoid tissues, we believe these preliminary data in B-NHL patients provide supporting evidence for our proposed mechanism of action in autoimmune disease. Using our cell therapy manufacturing platform, we have manufactured thousands of doses of cryopreserved, infusion-ready AlloNK cells from a single cord blood unit. We believe the design of AlloNK creates the potential for administration in the community setting and the scalability for broad commercialization, if approved.

NK Cell Background

NK cells are part of the innate immune system, which is the body's first line of immune surveillance and defense. NK cells modulate their activity through a balance of activating and inhibiting receptors on their surface that engage with their environment including with target cells. This balance enables NK cells to recognize and kill abnormal cells while suppressing cytotoxic responses to normal tissue, thereby providing a population of immune effector cells that defend against cancer and virus-infected cells. NK cells naturally work in concert with antibodies. The antibody first binds to a target on a diseased cell, then to the NK cell via the cell-surface receptor CD16, also known as FcγRIII, which engages the antibody to mount an ADCC response. NK cells may have an advantage over other immune cells, such as the T-cells used in CAR-T cell therapy and other cell therapies, because they can be used as allogeneic therapies, meaning that NK cells from one donor can be administered to one or many patients without the requirement for gene editing or other genetic manipulations.



Schematic of NK Cell Receptor Interaction with Target Cells. NK Cell Activation via ADCC Leads to NK-mediated Cytotoxic Activity

To produce AlloNK, we select cord blood units that have a variant of CD16 known as 158 V/V, which has been shown in preclinical studies to lead to increased ADCC activity. The CD16 158V/V point mutation variant encodes for a FcγRIII receptor that has been shown in preclinical studies to have higher affinity for immunoglobulin G mAbs. In a third-party clinical trial of rituximab, a significantly higher response rate was seen in follicular lymphoma patients with the CD16 genotype encoding the 158 V/V compared to those with other CD16 genotypes. As such, we believe NK cells sourced from donors with the CD16 158 V/V allele will have naturally higher affinity for therapeutic mAbs without the need for genetic engineering of the cell therapy product candidate.

AlloNK, as a non-genetically modified, non-targeted NK cell, is designed to utilize a mAb for targeting. Therefore, we believe different mAbs could be used to target distinct B-cell populations based on the target cell's antigen expression. For instance, CD19 and CD20 are expressed on memory B-cells, whereas CD38 and BCMA are expressed on plasma cells. Therefore, we believe AlloNK could be combined with different mAbs to kill distinct B-cell populations.

B-NHL Readthrough to Autoimmune Disease

We believe the success of cell therapies such as auto-CAR-T in oncology has paved the way for the application of cellular therapies in autoimmune diseases. Auto-CAR-T's clinical therapeutic benefit in autoimmune disease appears to be driven by a rapid and deep depletion of B-cells in the periphery and in the lymphoid tissues, followed by an immunological reset and B-cell reconstitution.

In the B-NHL setting, activity is also driven by deep depletion of B-cells, including cancerous B-cells in the periphery, and in the tissues where lesions are located, principally the lymphoid tissue. Peripheral B-cell levels can be measured in B-NHL patients, providing evidence of depletion of targeted cells in the periphery. CRs in B-NHL are assessed using the Lugano 2014 criteria which utilizes 18-fluorodeoxyglucose (FDG) PET/CT. CRs in B-NHL patients indicate disappearance of cancerous B-cells from lymphatic tissues, and therefore provide evidence that a therapy is targeting and eliminating cells of B-cell origin within tissues. An array of autoimmune diseases are driven by pathologic B-cells, and therefore, we believe observations of the pharmacodynamic response of a therapy or product candidate against cancerous B-cells in the periphery and in tissue in NHL patients can provide supporting evidence for the mechanism in autoimmune disease.

AlloNK Data in B-NHL

As of April 30, 2024, we had dosed 29 patients with AlloNK in combination with rituximab in our ongoing Phase 1/2 multicenter clinical trial in patients with relapsed or refractory B-NHL. The median age of the 29 patients dosed with AlloNK in combination with rituximab was 71 (range: 46 to 86), and patients had received a median of three prior lines of systemic treatment.

As part of this trial, we have assessed peripheral B-cell levels in patients before and after treatment with the combination of AlloNK and rituximab. In all 29 patients with samples analyzed, as of March 26, 2024, following the first cycle of treatment, all patients achieved non-quantifiable peripheral B-cell levels by Day 8 (except for one patient who achieved such B-cell depletion by Day 15) following the start of therapy, regardless of B-cell levels at baseline. Preliminary data, as of March 26, 2024, as described in further detail below, show peripheral B-cell depletion over the first cycle of treatment in all patients with detectable B-cells at baseline. We believe these preliminary data provide support for our proposed B-cell depleting mechanism of action.

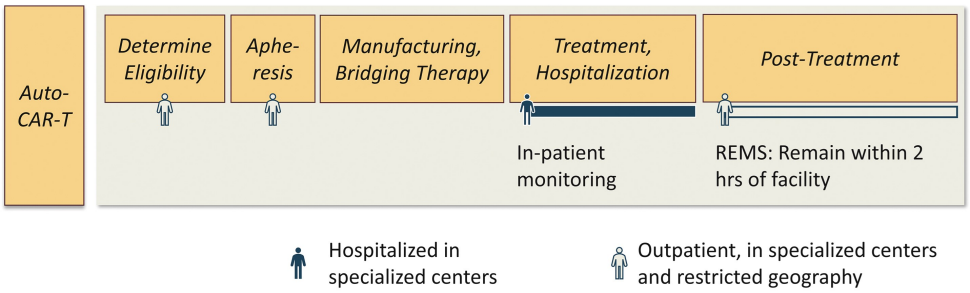
AlloNK has also shown CRs in B-NHL patients, as measured using the Lugano 2014 criteria by imaging of tumor lesions, in our ongoing clinical trial. Because of the common tissues of interest, principally the lymphoid tissues, in B-NHL and autoimmune diseases, we believe data in these B-NHL patients may provide supporting evidence for our proposed mechanism of action in autoimmune disease.

As described further below, in the Phase 1 portion of this trial, as of April 30, 2024, in the fourteen patients who were naïve to CAR-T, the ORR was 71%, including eight CRs (57%) and two PRs (14%), as determined by the Lugano 2014 criteria. Thirteen of these patients had aggressive forms of B-NHL, and the CR rate in this subset, as determined by the Lugano 2014 Criteria, was 62%. As of the April 30, 2024 data cutoff date, six of the eight patients

with a CR had an ongoing response (meaning continuation of the CR at all follow-up points), with five of these patients remaining progression free at six months or later. The longest responder remained progression free for at least 18 months after the start of treatment.

AlloNK Patient Journey

We believe AlloNK will improve the patient and physician experience when compared to the administrative complexity and management of potential toxicities associated with auto-CAR-T. This is in contrast to auto-CAR-T, which involves multiple steps that may materially delay time to treatment including a pre-treatment eligibility determination, apheresis within a specialized center, a wait period for auto-CAR-T manufacturing, infusion scheduling and finally receipt of cryopreserved auto-CAR-T in preparation for treatment. In addition, current Risk Evaluation and Mitigation Strategy programs for commercial auto-CAR-T requires patients to remain within two hours of the treatment center for four weeks following treatment (if healthcare providers require in-patient monitoring).



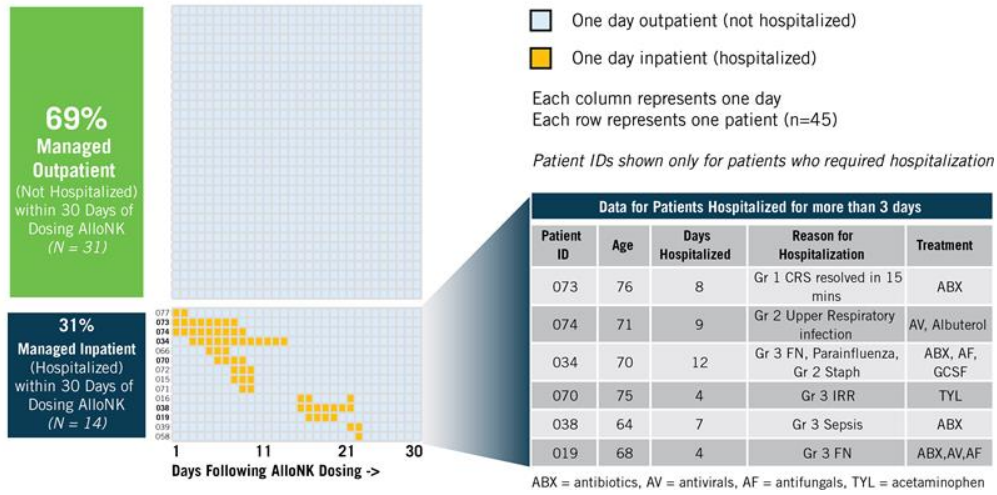
Illustrative Patient Journey on Auto-CAR-T Treatment

In contrast, AlloNK is an off-the-shelf cell therapy candidate that is cryopreserved with established end-to-end cold-chain logistics in place to enable a patient to start treatment without any prior steps. Further, AlloNK is logistically simple to administer and is in a format compatible with existing infusion center infrastructure. It is thawed at the bedside and administered in a 5-to-10 minute IV push without the need for any product formulation or processing.

In addition, AlloNK is designed to lend itself to an improved experience for the patient following treatment and we believe this will broaden access to the community setting. This is in contrast to auto-CAR-T, where mandatory hospitalization is often required in order to observe for side-effects such as CRS and ICANS. We believe AlloNK has the potential to enable rheumatologists to treat patients in their own infusion centers as opposed to having to refer patients to tertiary care centers. In preliminary data as of April 8, 2024, from our ongoing Phase 1/2 B-NHL trial, CRS was observed in four patients (9%) and of these patients, three patients experienced a Grade 1 CRS, one patient had a Grade 2 CRS, and no ICANS was observed.

The figure below shows the number of drug-related hospitalization days for the 30 days following dosing of AlloNK for all 45 B-NHL patients who received AlloNK in combination with rituximab in our Phase 1/2 clinical trial as of April 8, 2024. As shown in the figure below, 31 patients (69%) were treated entirely in the outpatient setting and were not hospitalized for adverse events during the first 30 days following administration of AlloNK in combination with rituximab dosing. Out of the 14 patients who were hospitalized, the median length of hospitalization was three days and the reasons for hospitalizations were related to fevers and infections. Further, these were heavily pre-treated elderly patients with a median age of 68 years and median four prior lines of therapy. Because of the advanced aged and frailty of this patient population, several hospital stays were extended to accommodate the next dose of AlloNK in combination with rituximab or in an abundance of caution. We believe these preliminary data support that AlloNK in combination with B-cell targeted mAbs has the potential to be

administered and managed in the community setting, which, if approved for such use, has the potential to expand access to more patients and alleviate economic and logistical burden on the healthcare system.



Number of Hospitalization Days Due to Drug-related Adverse Events in 45 Patients Treated with AlloNK in Our Phase 1/2 B-NHL Trial

AlloNK Lends Itself to a Breadth of Targeting Approaches and Indications

AlloNK, as a non-genetically modified, non-targeted NK cell, utilizes a mAb for targeting. Therefore, different mAbs could be used to target distinct B-cell populations based on the target cell's antigen expression. Beyond rituximab and other anti-CD20 mAbs, we have already conducted numerous preclinical studies in which we have shown cytotoxic activity of AlloNK in combination with other approved B-cell targeted mAb therapies, such as anti-CD19 and anti-CD38 mAbs. Emerging evidence with auto-CAR-T targeting the plasma cell antigen BCMA has shown therapeutic activity in several indications, and we believe AlloNK in combination with approved anti-CD38 mAbs could target a similar plasma cell population. We have the opportunity to develop AlloNK in combination with approved B-cell targeted mAbs using a variety of targets, including the potential for dual targeting by treating in combination with two mAbs. We believe this versatility will enable us to pursue a wider range of indications than cell therapies engineered against specific targets.

AlloNK Development in Autoimmune Diseases

AlloNK is an allogeneic, off-the-shelf, cryopreserved NK cell therapy candidate designed to enhance the ADCC effect of mAbs to drive B-cell depletion. AlloNK is designed to be administered in the community setting. Using our proprietary cell therapy manufacturing platform, we can generate thousands of doses of cryopreserved, infusion-ready AlloNK from a single cord blood unit.

We are currently evaluating AlloNK in combination with rituximab or obinutuzumab in a Phase 1/1b open-label multi-center clinical trial in patients with SLE with or without LN who previously failed treatment, for which the FDA has granted Fast Track designation to improve disease activity in patients with class III or class IV LN. In addition, in April 2024, the FDA cleared an IND submitted by IRIS, a large community practice rheumatology clinic in Florida, to conduct a basket IIT to assess the safety, tolerability and clinical activity of AlloNK in combination with rituximab in patients with RA, PV, GPA / MPA and SLE. Treatment of the first patient in the basket IIT was initiated in August 2024. We intend to pursue additional autoimmune diseases with AlloNK in combination with B-cell targeted mAbs.

SLE and LN Background

SLE is an autoimmune disease characterized by autoantibody production and deposition of immune complexes with complement activation, resulting in inflammation and damage within the affected tissue, which contributes significantly to the disease's morbidity and mortality rates. LN, a type of kidney disease, is a manifestation of SLE reported to affect approximately half of all patients with SLE. LN occurs when autoantibodies affect parts of the kidneys that filter out waste, which can result in swelling, weight gain from fluid retention, elevated blood pressure and urine that appears foamy from excessive protein loss. Diagnosis often reveals proteinuria, or the presence of excessive protein in the urine, blood in the urine, and lowered serum albumin levels.

The primary aim of managing LN involves preventing irreversible kidney damage, typically through anti-inflammatory and immunosuppressive therapies like steroids, MMF and cyclophosphamide to alleviate inflammation and blood pressure medications that protect the kidneys. Despite the availability of potent therapies, up to 10% of LN patients still progress to end-stage renal disease, requiring dialysis and eventually, a kidney transplant. There are an estimated 210,000 SLE patients with LN across the United States and Europe, and approximately 30% do not respond to currently available treatments. Furthermore, chronic use of these therapies typically creates secondary complications for patients, including, but not limited to, increased risk of infections and cancer, cardiovascular disease, hypertension, Cushing's disease, diabetes and osteoporosis.

Rationale for AlloNK in SLE and LN

We are focusing on SLE and LN as the first target of our clinical development program in light of the clearly identifiable patient group, significant unmet need and presence of measurable clinical endpoints to facilitate regulatory approval submissions.

LN offers an objective clinical marker for tracking disease activity and renal impairment: proteinuria. This marker enables the use of the UPCR to assess renal function, making it a reliable and objective endpoint. The reduction of proteinuria, as determined by UPCR, is an important component of CRR, which has been historically used as a critical measure to evaluate a patient's response to treatment for LN in clinical trials.

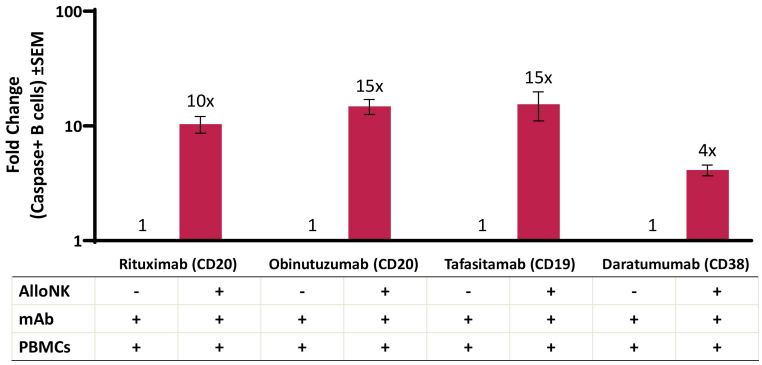
B-cells are recognized as key mediators of SLE pathogenesis and B-cell targeted mAbs direct B-cell killing via ADCC and induction of apoptosis. However, studies have shown that B-cell depletion is incomplete in the tissues of certain patients following rituximab treatment, leading to pathogenic B-cell escape and hindering effective reset of the immune system. NK cells from SLE patients have been shown to be reduced in number in peripheral blood, with reports of SLE patients having less than half as many CD16+ NK cells as healthy subjects. Further, the phenotype of NK cells in SLE patients can result in reduced cytotoxicity as well as defective ADCC, which could lead to incomplete B-cell depletion by rituximab. In several preclinical studies, AlloNK potentiated anti-CD20-mediated ADCC against CD20-expressing malignant B-lymphocytes in vitro and in vivo and was not negatively affected by steroids. Further, AlloNK induced B-cell apoptosis in combination with rituximab and obinutuzumab in peripheral blood mononuclear cells (PBMCs) isolated from SLE patients.

AlloNK Preclinical Results in SLE and LN

In vitro preclinical studies, we evaluated the cytotoxic activity of AlloNK in combination with rituximab or obinutuzumab mAbs against PBMCs isolated from SLE patients. PBMCs combined with thawed AlloNK were incubated with or without antibodies (0.0.01, 0.1.1 ug/mL) at different effector (AlloNK cell) to target (PBMCs) ratios (E:T ratios) for four hours. The E:T ratios tested were 0.2:1, 1:1, and 2:1 AlloNK to PBMCs. Apoptotic (caspase positive) B-cells in SLE PBMCs were quantified by flow cytometry.

ADCC against SLE B-cells was observed when AlloNK was combined with rituximab or obinutuzumab in an antibody concentration-dependent and an E:T ratio-dependent manner. Shown below is data from an E:T ratio of 1:1 at a single antibody concentration. The specificity of cell killing in the SLE PBMC sample was evaluated by examining the effects of the combination on SLE T-cells. Importantly, little to no off-target apoptosis was observed in this cell population in the presence of AlloNK and either of the antibodies tested. In addition to anti-CD20 mAbs, we have conducted in vitro preclinical studies of AlloNK in combination with tafasitamab, an anti-CD19 antibody, or daratumumab, an anti-CD38 antibody, which demonstrated specific killing of B-cells from SLE PBMCs.

Data below shows fold change in B-cell killing when mAb (0.1µg/mL) was combined with AlloNK in a 1:1 ratio with SLE PBMCs (n=3–6 SLE PBMC donors). Increased B-cell apoptosis was observed when AlloNK was combined with B-cell targeting mAbs, which we believe demonstrates enhanced ADCC with the mAb combinations.



	Rituximab (CD20)		Obinutuzumab (CD20)		Tafasitamab (CD19)		Daratumumab (CD38)	
AlloNK	-	+	-	+	-	+	-	+
mAb	+	+	+	+	+	+	+	+
PBMCs	+	+	+	+	+	+	+	+

Fold Change in B-cell Killing when AlloNK was Added to mAb in SLE PBMCs. AlloNK was Added in a 1:1 ratio to PBMCs, with mAb at 0.1µg/mL (n=3–6 SLE PBMC donors)

AlloNK Clinical Development in SLE and LN

In April 2024, we began dosing patients in our Phase 1/1b open-label, multi-center clinical trial of AlloNK in combination with rituximab or obinutuzumab in patients with class III or class IV LN who previously failed treatment. We also amended the protocol for this trial to broaden the patient population to include patients with SLE without LN. The trial is designed as a two-stage trial. We plan to enroll up to six patients per cohort in dose escalation (stage 1) with a 3+3 design, and up to a total of 12 patients per cohort in the cohort expansion (stage 2), inclusive of those patients from the corresponding cohort in stage 1.

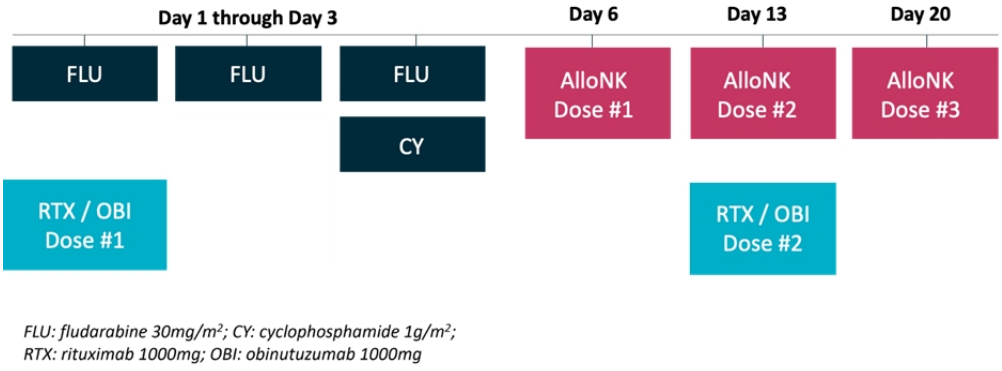
AlloNK dosing will start at one billion total cells per dose, and the rituximab cohort can enroll in parallel with the obinutuzumab cohort. The protocol allows dose escalation to four billion total cells per dose, with rituximab and obinutuzumab combination cohorts enrolling in parallel. Other than the first patient in each cohort, who will be hospitalized overnight following the first dose of AlloNK only, no other patients have any mandatory hospitalization requirement per the trial protocol.

The primary objective of the clinical trial is to assess the safety, tolerability and preliminary activity of AlloNK in combination with rituximab or obinutuzumab. The primary efficacy endpoint is the overall renal response rate (ORRR) defined as the proportion of subjects having either a complete renal response (CRR) or partial renal response (PRR) at 52 weeks. A CRR is defined as achieving a UPCR of less than 0.5 and normal renal function as determined by serum creatinine levels at or below the upper limit of normal without worsening of baseline serum creatinine by more than 15%. A PRR is defined as a 50% or more reduction in UPCR from baseline, to an absolute value of less than one, or to less than three if baseline UPCR was above three, and serum creatinine not increased by more than 15% from baseline. We will also collect global disease activity measurements using the SLEDAI-2K assessment, and translational biomarkers, including levels of autoantibodies, serum complement, serum immunoglobulins, and peripheral B-cell subsets.

In auto-CAR-T studies, an initial lymphodepletion regimen has been utilized consisting of cyclophosphamide and fludarabine, which depletes B-cells among other lymphocytes. Our clinical development approach in SLE and LN is to investigate our product candidate utilizing a similar initial lymphodepletion regimen followed by treatment with AlloNK in combination with a B-cell targeted mAb. We may explore ways to optimize and possibly remove the lymphodepletion regimen in future development.

We utilize combination with rituximab to target CD20, an antigen present on B-cells in many of the same lineages that express CD19. In a clinical study of rituximab in SLE published by Vital *et al.* in 2011, when complete depletion of CD20-expressing B-cells was achieved, depletion of CD19-expressing, CD20-negative plasmablasts was also observed, suggesting that CD20 targeting can potentially deplete a broad range of B-cells, including plasmablasts. Further, in our B-NHL trial, AlloNK in combination with rituximab was observed to drive deep B-cell depletion in the periphery, as measured by CD19 expression, which we believe indicates that this regimen can potentially deplete CD19-expressing B-cell lineages. We believe this has the potential to mirror the approach of auto-CAR-T cell therapy in achieving an initial, generalized lymphodepletion before attacking the pathogenic B-cells, with the goal of achieving deep B-cell depletion. In the NOBILITY Phase 2 clinical study of obinutuzumab in LN, published by Furie *et al.* in 2022, obinutuzumab was superior to placebo for the achievement of CRR and ORR in patients with proliferative LN when added to mycophenolate (median 2g/day) and corticosteroids, indicating that obinutuzumab may be an attractive mAb to combine with AlloNK in order to achieve deep B-cell depletion. In a post-hoc analysis of the NOBILITY clinical study, presented by Vital *et al.* in 2024, the subset of patients with sustained B-cell depletion at weeks 24 and 52 achieved a 50% CRR at week 76, making these patients 72% more likely to achieve a CRR at week 76 than the subset of patients who had unsustained B-cell depletion.

The treatment schedule is outlined below. The lymphodepletion treatment regimen consists of three daily doses of 30 mg/m^2 fludarabine and a single dose of 1000 mg/m^2 cyclophosphamide, a very similar regimen as utilized in studies led by Schett. Rituximab or obinutuzumab is given in two doses of 1000 mg each, the same regimen used in autoimmune indications such as RA. AlloNK is given in three weekly doses at either one billion or four billion total cells per dose. All patients will receive at least one treatment cycle followed by scheduled assessments of overall health and response status. Patients who have not achieved a CRR are eligible for a second cycle, as described above, at six months. We dosed our first patient in this trial in April 2024, and the DLT assessment period has been cleared.



Treatment Regimen for AlloNK in Combination with B-cell Targeted mAbs in a Phase 1/1b Trial in SLE and LN

AlloNK Development in Additional Autoimmune Indications

We believe that AlloNK has the potential to impact multiple additional B-cell mediated autoimmune indications beyond SLE and LN. We are exploring the potential of AlloNK in these indications and other antibody combinations through company-sponsored clinical trials and by supporting IITs.

We believe supporting IITs, where we provide patient access to AlloNK by supplying AlloNK for use in IITs, allows us to prioritize patient needs while providing us insight that has the potential to support expansion of our development programs into additional indications where we believe AlloNK in combination with B-cell targeted mAbs has the potential to benefit patients who are refractory to existing therapies.

B-cell depletion has a therapeutic activity in multiple additional autoimmune indications as evidenced by indications where mABs targeted against CD20 such as rituximab and ocrelizumab are approved, as well as data from the study led by Schett. These indications include RA, PV and GPA, formerly known as Wegener's granulomatosis, MPA, IIM, SSc, MG and MS.

Rituximab is approved for certain RA, PV, and GPA / MPA indications. RA is a chronic inflammatory disorder that primarily affects joints, but can also have systemic effects, impacting various organs and tissues in the body. PV is a rare, chronic autoimmune disorder characterized by antibodies against desmogleins and the formation of blisters and erosions on the skin and mucous membranes, most commonly affecting the mouth, throat, nose, eyes, genitals and lungs. AAV is a group of rare autoimmune diseases of unknown cause characterized by anti-neutrophil cytoplasmic antibodies, and encompassing the subtypes GPA, which affects various organs, including the kidneys, lungs and upper respiratory tract, and MPA, which often involves the kidneys and lungs but can affect any organ system.

The Schett group developed clinical data, which we believe support the potential of B-cell depleting cell therapy in treating IIM and SSc. IIM is a group of autoimmune conditions characterized by inflammation of muscle (myositis) and other organ systems, resulting in widespread organ dysfunction. For patients with severe disease, symptoms can be debilitating, and can lead to mortality, especially when lungs are involved. SSc is a persistent, systemic autoimmune disease characterized by autoantibodies against transcriptional and translational components, including topoisomerase, centromeres and RNA polymerase, resulting in vascular damage and fibrosis. A significant portion of SSc patients develop interstitial lung disease (ILD), and for those who develop pulmonary hypertension, the three-year mortality rate exceeds 60%.

B-cell depletion has also shown therapeutic effects in neuroinflammatory diseases like MS and MG. MS is a long-term condition affecting the central nervous system, leading to neurodegeneration caused by inflammation. Ocrelizumab, a B-cell targeting anti-CD20 mAB, was approved in 2017 for treatment of relapsing MS and primary progressive MS, underscoring the role of B-cells in influencing relapse frequency and disease advancement in MS. MG is a chronic autoimmune disorder in which antibodies destroy the communication between nerves and muscle, resulting in weakness of the skeletal muscles, and case reports have shown an impact of B-cell-targeted auto-CAR-T.

In these other autoimmune and neuroinflammatory diseases, some patients with severe disease or who are refractory to prior therapies require continuous treatment with immunosuppressive regimens, including steroids, leading to long-term health consequences. We believe a therapy that could allow for a period of drug-free remission could therefore fill a significant unmet need for patients.

Investigator-Initiated Basket Trial

In April 2024, the FDA cleared an IND submitted by IRIS, a large community practice rheumatology clinic in Florida, to conduct a basket ITT to assess the safety, tolerability, and clinical activity of AlloNK in combination with rituximab. The IIT will initially enroll patients with RA, PV, GPA / MPA and SLE.

The IIT is a basket trial, which is a clinical trial that evaluates how well a therapy works in patients with different diseases that share a common characteristic, such as different autoimmune indications. The basket design utilizes an initial safety run-in stage of nine all-comers patients with any of the four included indications, followed by expansion cohorts to enroll a total of six patients per cohort for PV and GPA /MPA, and nine patients per cohort for RA and SLE. All patients will receive a single cycle of treatment, consisting of cyclophosphamide and fludarabine lymphodepletion, rituximab, and AlloNK. The dosing regimen leverages the standard of care dose and schedule of rituximab for each indication, with AlloNK given in three weekly doses of one billion total cells per dose. Other than the first patient in each cohort, who will be hospitalized overnight following the first dose of AlloNK only, no other patients have any mandatory hospitalization requirement per the trial protocol. The primary objective of the clinical trial is to assess the safety, tolerability and preliminary activity of AlloNK in combination with rituximab. Primary efficacy endpoints specific to each indication (RA, PV, GPA / MPA and SLE) will be used. We also anticipate assessing translational biomarkers, including levels of autoantibodies relevant in each indication, serum complement levels, serum immunoglobulin isotypes, peripheral B-cell subsets, and peripheral levels of AlloNK for pharmacokinetic analysis. Treatment of the first patient in the basket IIT was initiated in August 2024.

Pursuant to an institution-initiated and sponsored clinical trial agreement with IRIS, we are providing support and supply AlloNK and funding for study-related expenses for the IIT, but unlike our sponsored clinical trials, IRIS is the regulatory sponsor of, and responsible for the conduct of the IIT. This IIT is not part of our clinical trials for AlloNK and data from this trial is reported by the relevant investigator. While we do not expect to be able to use the results from this IIT in our applications for marketing approval to the FDA or other comparable foreign regulatory agencies, we believe that this strategy may provide some competitive advantage as we will be able to acquire additional clinical insights beyond highly focused clinical trials in specific geographies and additional indications.

AlloNK Development in Non-Hodgkin Lymphoma

Non-Hodgkin Lymphoma Background

NHL is a neoplasm of the lymphoid tissues originating from B-cell precursors, mature B-cells, T-cell precursors and mature T-cells. Approximately 85% are B-cell malignancies. Currently available NHL treatments like auto-CAR-T products targeting CD19 have shown promise in aggressive lymphomas but we believe they are associated with life-threatening safety risks, have limited access and are slowly administered due to manufacturing inefficiencies.

AlloNK Clinical Development in B-NHL

We have tested AlloNK in combination with rituximab in 29 patients with relapsed or refractory B-NHL in our ongoing Phase 1/2 clinical trial with data, as of an April 30, 2024 cutoff date. The clinical trial also enrolled 16 patients in monotherapy cohorts, consisting of lymphodepletion and AlloNK without rituximab. The Phase 1 portion of the study is evaluating two AlloNK dose levels, four-weekly doses of either 1 billion cells or 4 billion cells per dose, as monotherapy or in combination with rituximab using the 3+3 dose escalation method. The primary objective of the clinical trial is to assess the safety and anti-tumor activity of AlloNK in combination with rituximab.

In our trials, clinical activity is primarily determined by responses as measured by the Lugano 2014 criteria using both modalities as described in the table below. The criteria classify clinical activity or treatment response as CR, PR, stable disease or progressive disease. The Lugano classification recommends the Deauville five-point scale for reporting response by FDG PET-CT. The Deauville five-point scale scores responses as follows (where 1 is best and 5 is the worst): (1) no uptake or no residual uptake (when used interim), (2) slight uptake, but equal to or below blood pool (mediastinum), (3) uptake above mediastinal, but below or equal to uptake in the liver, (4) uptake slightly to moderately higher than liver or (5) markedly increased uptake or any new lesion (on response evaluation). A summary of the Lugano 2014 criteria is described below.

	CT-Based Response	**FDG PET-CT-Based Response**
Complete Response	Lymph nodes ≤ 1.5 cm in LDi Complete disappearance of radiologic evidence of disease	Scores 1, 2, 3 (Deauville scale) in nodal or extranodal site with or without a residual mass Complete metabolic response
Partial Response	Single lesion: 50% or greater decrease in SPD of up to six lymph nodes or extranodal sites	Scores 4 or 5 (Deauville scale) with decreased uptake compared with baseline and residual mass(es) of any size
Stable Disease	Less than 50% decrease in SPD of up to six lymph nodes or extranodal sites (no criteria for progressive disease are met)	Scores 4 or 5 (Deauville scale) with no significant change in FDG uptake
Progressive Disease	1) New lymphadenopathy or increased; single node must be abnormal with: a) LDi > 1.5 cm and b) PPD ≥ 50% and c) LDi or SDi increased 0.5 cm if ≤ 2.0 cm and increased 1.0 cm if > 2.0 cm 2) Increased splenic volume:	Scores 4 or 5 (Deauville scale) In any lesion with increased uptake from baseline and/or new FDG-avid focus consistent with malignant lymphomai

	CT-Based Response	FDG PET-CT-Based Response
	a) with prior splenomegaly: greater than 50% increase of its prior increase beyond baseline b) without prior splenomegaly: greater than 2.0 cm increase c) New or recurrent splenomegaly 3) New or clear progression of preexisting nonmeasured lesions 4) Regrowth of previously resolved lesions 5) New extranodal lesion > 1.0 cm in any axis (new lesions < 1.0 cm in any axis are included if presence is unequivocal and attributable to lymphoma) 6) A new node > 1.5 cm in any axis 7) Assessable disease of any size if unequivocally attributable to lymphoma	

LDi = longest transverse diameter; **SDi** = shortest transverse diameter; **PPD** = product of perpendicular diameters; **SPD** = sum of the product of the perpendicular diameters of multiple lesions; **FDG** = fluorodeoxyglucose

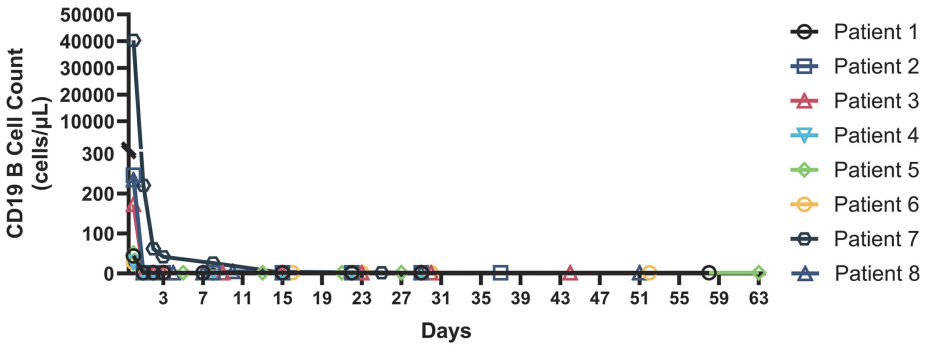
Lugano 2014 Criteria Table For Lymph Nodes and Extralymphatic Sites

All patients receive lymphodepleting chemotherapy for three days prior to treatment of AlloNK and low-dose subcutaneous IL-2 after each dose of AlloNK. Patients in the combination cohorts received up to two cycles of treatment with lymphodepletion, with the third and fourth cycle, if eligible, given without lymphodepletion. A third cohort was added to test a bi-weekly dosing schedule of AlloNK in combination with rituximab but without the administration of IL-2. Patients in this cohort received up to three cycles of treatment with lymphodepletion. Any patient experiencing clinical benefit (stable disease (SD), PR or CR, per the Lugano 2014 criteria) after one cycle of treatment with AlloNK and rituximab is eligible for additional cycles of AlloNK plus rituximab. The median age of the 29 patients dosed with AlloNK in combination with rituximab was 71 (range: 46 to 86), and patients had received a median of three prior lines of systemic treatment.

B-cell Depletion in B-NHL Patients

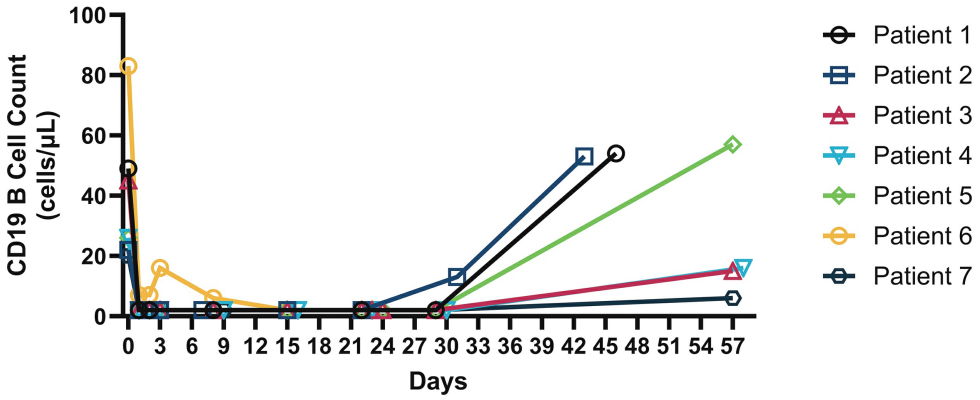
Blood samples were drawn at specified timepoints during the course of the trial. B-cell depletion was assessed in whole blood samples using the TBNK cells assay (BD Mulitest 6-color TBNK Reagent). In 29 patients treated with the combination of AlloNK and rituximab with samples analyzed, as of a March 26, 2024 cutoff date, we observed that all patients achieved non-quantifiable peripheral B-cell levels by Day 8 (except for one patient who achieved such B-cell depletion by Day 15) following the start of a single cycle of therapy, regardless of B-cell levels

at baseline. Preliminary data below, as of March 26, 2024, demonstrates peripheral B-cell depletion over the first cycle of treatment in all patients with detectable B-cells at baseline.



Peripheral Depletion of CD19+ B-cells in NHL Patients Treated with AlloNK and Rituximab

Further, we assessed peripheral B-cell levels in patients treated in the monotherapy cohorts. Data, as of May 15, 2024, showed initial non-quantifiable peripheral B-cell depletion in seven monotherapy patients with detectable B-cells at baseline. This B-cell depletion was maintained in the majority of patients through approximately four weeks after the initial AlloNK dose. In contrast to the combination therapy cohorts, B-cell levels in the monotherapy patients began to increase approximately four to eight weeks after the initiation of treatment.

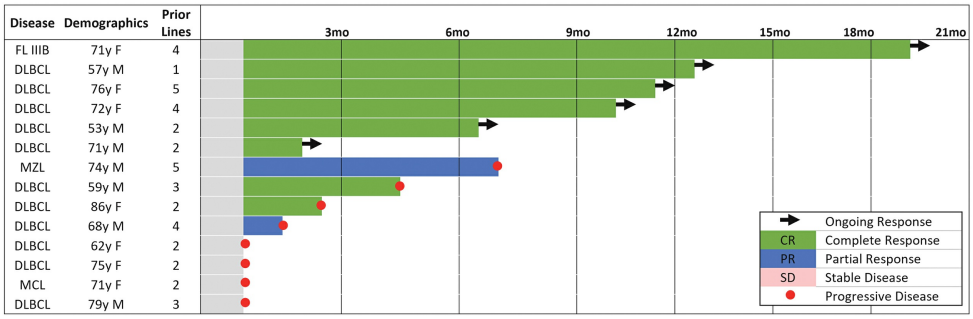


Peripheral Depletion of CD19+ B-cells in NHL Patients Treated in Monotherapy Cohorts (Lymphodepletion and AlloNK without Rituximab)

Clinical Responses in B-NHL Patients

Of the 29 patients treated with AlloNK in combination with rituximab, as of April 30, 2024, 14 patients (48%) were not exposed to prior CAR-T. In these patients, the ORR was 71%, including eight CRs (57%) and two PRs (14%). Thirteen of these 14 patients had aggressive forms of NHL, with one patient having indolent marginal zone lymphoma but having previously failed five prior lines of therapy. As of the April 30, 2024 data cutoff date, six of the eight patients with a CR had an ongoing response (meaning continuation of the CR at all follow-up points), with

five of these patients remaining progression free at six months or later. The longest responder remained progression free for at least 18 months after the start of treatment.



Clinical Responses of AlloNK in Combination with Rituximab in All Patients Naïve to Prior CAR-T in Phase 1/2 B-NHL Trial

Fifteen patients (52%) treated with AlloNK in combination with rituximab received prior CAR-T, of which 13 (45%) received commercial auto-CAR-T-therapies. The ORR in the 15 patients exposed to prior cell therapies was observed to be 40% including four CRs and two PRs.

Preliminary Safety Data

As of April 8, 2024, a total of 45 patients were evaluated for safety across all cohorts in our Phase 1/2 B-NHL trial (16 monotherapy and 29 in combination with rituximab). The median age at enrollment was 68 years and patients had a median of four prior lines of systemic therapy. All, except for one monotherapy patient, received prior anti-CD20 mAb.

Only one dose-limiting toxicity (DLT) of an infusion-related reaction was observed across all combination cohorts. The maximum tolerated dose was not reached, and AlloNK at four billion cells per dose was deemed to be the maximum administered dose. CRS was observed in four of 45 patients (9%), with no Grade 3 or higher CRS reported. Three patients experienced a Grade 1 CRS and one patient had a Grade 2 CRS. Cytokine analysis of samples from 40 patients treated with AlloNK showed IL-6 concentrations below 100 pg/mL at all time points analyzed, including samples from the 4 patients where CRS was reported. These IL-6 levels were below the lower limit of the range typically associated with CAR-T-related CRS. No other cell therapy associated treatment emergent adverse effects were observed, including ICANS or graft-versus-host disease. Serious treatment emergent adverse events (TEAEs) occurred in almost half of the 45 patients treated across all cohorts, and the most common (experienced by two or more patients) were febrile neutropenia (11%), sepsis (9%), infusion-related reactions and malignant progression (7% each), and pneumonia and pyrexia (4% each). Serious TEAEs related to AlloNK were observed in seven out of 45 patients (16%) treated across all cohorts, and consisted of infusion-related reactions (7%), febrile neutropenia (4%), and CRS and pyrexia (2% each).

Among the 29 subjects treated with AlloNK in combination with rituximab, the most common severe (Grade ≥3) TEAEs reported were associated with hematological disorders, which we consider to be consistent with the usage of lymphodepletion in this patient population, and included leukopenia (86%), neutropenia (83%), lymphopenia (76%), anaemia (45%) and thrombocytopenia (28%). The only other TEAEs observed in ≥10% of the

patients treated with AlloNK in combination with rituximab were febrile neutropenia (10%), sepsis (10%) and infusion-related reactions (10%).

System Organ Class (SOC)/ Preferred Term, n (%)	Rituximab Combination (n=29)	Overall (n=45)
Leukopenia	25 (86)	36 (80)
Neutropenia	24 (83)	36 (80)
Lymphopenia	22 (76)	30 (67)
Anaemia	13 (45)	14 (31)
Thrombocytopenia	8 (28)	9 (20)
Febrile neutropenia	3 (10)	6 (13)
Sepsis	3 (10)	4 (9)
Infusion-related reaction	3 (10)	3 (7)

Grade 3 or higher treatment emergent adverse events (TEAEs) observed in ≥10% of the patients treated with AlloNK in our Phase 1/2 clinical trial in B-NHL

Partnered Programs

AlloNK in HL

Our ongoing collaboration with Affimed involves investigating AlloNK in combination with acimtamig, a CD30-targeted NK cell engager, in HL and potentially other CD30+ cancers. Classical HL is a type of cancer that originates from lymphocytes, leading to the growth of abnormal cells in the lymphatic system. The disease is characterized by the presence of Reed-Sternberg cells which highly express the CD30 antigen, making CD30 a crucial target for certain therapies and a marker for diagnosing and monitoring the disease's progression. Preclinical data showed *in vitro* cytotoxicity and in vivo anti-tumor activity with AlloNK, in combination with acimtamig, against a CD30+ T-cell lymphoma cell line.

In November 2022, we announced a strategic partnership to jointly develop, manufacture, and, if approved, commercialize a combination therapy comprising of acimtamig with AlloNK. Affimed chose us as a partner to commercialize the combination based on the preclinical and clinical evidence of activity of AlloNK observed in NHL to date and our manufacturing expertise to provide cryopreserved NK cells for a muti-center trial and the potential to produce a cryopreserved, off-the-shelf, commercially-viable product.

Under the agreement, Affimed will lead regulatory activities through clinical development and, if approved via the accelerated approval pathway, any confirmatory studies. Affimed will be responsible for funding clinical study costs, while we will be responsible for the costs of supplying AlloNK and IL-2 for such studies. If accelerated approval is obtained, we may continue in the collaboration and share confirmatory study costs on a 50/50 basis, and in return revenues from the combination will be shared in a proportion of 67%/33% (Affimed/Artiva). Affimed will be responsible for promotional activities and expenses of the combination therapy, if approved. We retain commercialization and distribution rights and books sales for AlloNK.

The Phase 2 LuminICE-203 trial is currently enrolling patients with relapsed or refractory HL, and Affimed presented initial data from the first 22 patients in December 2024. The initial run-in phase is evaluating four cohorts with two doses of acimtamig and two doses of AlloNK. In each cohort, patients are given an initial lymphodepletion regimen of cyclophosphamide and fludarabine, followed by six weekly treatments. The first three weekly treatments consist of acimtamig infusion, followed by infusion of AlloNK and IL-2. The last three weekly treatments consist of

acimtamig infusion alone. Following the run-in portion, the trial will follow a Simon two-stage design, with up to two dose cohorts tested in Stage 1 and one-to-two cohorts in Stage 2. The trial will also include an exploratory cohort in peripheral T-Cell lymphoma (PTCL).

CAR-NK Programs

Our manufacturing platform also allows for the generation of CAR-targeted NK cells utilizing cord blood starting material with the same pre-selected characteristics and scale-up process as AlloNK. We own ex-APAC rights for AB-201, a HER2 targeting CAR-NK cell, and for AB-205, a CD5 directed CAR-NK.

Platform to Create Gene-Modified NK Cells

As an alternative to targeting NK cells to tumors by combining with mAb therapy or NK-engager bispecific technology, NK cells may be targeted directly through the addition of a CAR against a defined target antigen. This is accomplished through genetic modification of the NK cell and can also include the addition of cytokine transgenes to further enhance the activity and persistence of these CAR-NK cells. We believe these modifications can turn NK cells into the kind of flexible, potent and allogeneic therapy that CAR-T cells were intended to become. In particular, we believe that the potential therapeutic applications of NK cells can be expanded by two types of gene modifications:

1.Addition of CAR constructs to direct NK cells to specific antigens: We introduce CAR constructs to our cord-blood derived NK cells via a lentiviral vector. This virus vector is manufactured under cGMP conditions in the United States prior to being transferred to the GC Cell manufacturing facility in Korea where it is combined with NK cells during the first expansion phase of our manufacturing process. Our CAR constructs have been designed to enhance the activity of our NK cell product candidates based on extensive empirical evaluation of costimulatory domains alone and in combination. In our preclinical studies, CAR-NK cells that contain the costimulatory domain OX40L used in our CAR construct exhibited greater cytotoxic potential than structures used in other T-cell and NK cell programs.

2.Enhancement of viability and potency through overexpression of cytokines: IL-15 promotes NK cell viability, proliferation and function. Transduction of NK cells with gene constructs that lead to expression of IL-15 increased their cytotoxic potential in preclinical studies. Further, IL-15 expression has been associated with increased cell persistence in third-party human clinical studies. Expression of IL-15 in our CAR-NK cells has resulted in high viability in culture and our AB-201 product candidate expresses the IL-15 transgene. Our preclinical studies showed that the IL-15 co-expressed from the CAR lentivirus resulted in persistence of AB-201 cells in the circulation of mouse models beyond Day 30 and peak detection in lung and spleen tissues at Day 15. This was substantially longer than the persistence seen for cord blood-derived NK cells not expressing IL-15.

AB-201

AB-201 is an allogeneic anti-HER2 CAR-NK cell product candidate, containing a CAR with a proprietary HER2 antigen recognition domain and expressing soluble IL-15. HER2, also known as Human Epidermal Growth Factor Receptor 2 or ErbB2, is a receptor tyrosine kinase that is overexpressed on many solid tumors, such as breast, gastric and esophageal, and bladder cancers. AB-201 has shown specific cytotoxic activity against HER2+ tumor cells in vitro and anti-tumor activity and tumor infiltration in vivo. AB-201 is designed to bind to a region distinct from other HER2-targeting drugs, such as trastuzumab and pertuzumab. We have received orphan drug designation for AB-201 in the United States.

It is estimated that there are over 50,000 patients diagnosed annually in the United States with tumors having high expression of HER2, with overexpression found in approximately 10% to 15% of breast cancer cases and in over 10% of bladder and esophageal cancers. Many breast cancer patients with HER2+ localized disease experience pathologic complete responses when treated with HER2-directed therapies. However, for patients who relapse and for those who present initially with metastatic disease, current treatments can provide clinical responses but are not curative, and prognosis generally worsens with each subsequent line of therapy. HER2 is expressed in a subset of gastric, gastro-esophageal junction and esophageal cancers. Each year, over 5,000 patients in the United States begin various lines of treatment for HER2+ disease. Trastuzumab and fam-trastuzumab deruxtecan are approved for use in

HER2+ gastric cancer, but a significant unmet medical need remains with only about half of patients responding to these therapies in first-line treatment and fewer than 30% of patients responding in third and later lines. HER2 is also expressed in a subset of bladder cancers. Each year, over 5,000 bladder cancer patients in the United States receive treatment for cancer that expresses HER2, but there are no approved HER2-directed therapies in bladder cancer.

AB-205

AB-205 is an allogeneic anti-CD5 CAR-NK cell product candidate, containing a CAR with a CD5 antigen recognition domain and expressing soluble IL-15. CD5 is a T-cell activation marker and negative regulator of TCR signaling expressed on tumor cells in the majority of cases of T-cell lymphoma and leukemia. Our partner, GC Cell, has observed specific cytotoxic activity against CD5+ T-cell leukemia cell lines, CCRF-CEM and RPMI-8402, with AB-205 in vitro and meaningful anti-tumor activity in vivo.

CD5 is expressed in a large number of cases of T-cell lymphoma (TCL) and T-cell Acute Lymphoblastic Leukemia (T-ALL). TCL accounts for 10-15% of all NHL cases and is categorized as cutaneous (CTCL) or more aggressive PTCL forms. PTCL, which accounts for approximately half of TCL cases, can be further subdivided into subtypes, with an estimated 80% of all cases expressing CD5. The CD30-targeted antibody drug conjugate Adcetris (brentuximab vedotin, BV) is used in PTCL, with the highest efficacy in the anaplastic large cell lymphoma (ALCL) subtype which uniformly expresses CD30. However, approximately 15% of ALCL patients are refractory or quickly progress following BV, while another 50% of ALCL patients initially respond, but ultimately progress after BV. Further, efficacy of BV and expression of CD30 in other PTCL subtypes is varied. There remains an unmet need for effective and safe therapies in these populations.

CAR-NKs may be an especially advantageous construct for targeting cancers of T-cell origin because of two limitations of CAR-T cells. First, autologous CAR-T products must be generated from T-cells isolated by leukapheresis, and using cells from a patient as starting material may risk generating CAR-T product from cancerous T-cells which could result in secondary malignancy. Second, since CD5 is expressed on normal, activated T-cells, CAR-T products, whether autologous or allogeneic, may need to be engineered to avoid fratricide of CAR-T cells against other CAR-T cells.

Manufacturing Capabilities and Industrialization of NK Cell Therapy

We have a manufacturing-first approach, referencing the fact that even before we were founded, our strategic partner GC Cell had already invested years pioneering the manufacturing process that we use today. Unlike most other companies in the NK field who started clinical development before establishing a scalable manufacturing process, we started clinical development with a mature and robust process in place. Our process is designed to allow us to produce off-the-shelf, allogeneic NK cell therapy candidates at scale, with the mission to make these therapies broadly accessible for patients with devastating autoimmune diseases and cancers. We leveraged our deep expertise in NK cell biology to establish an end-to-end proprietary process in collaboration with our strategic partner, GC Cell.

We believe the following features of our platform provide multiple key advantages:

Cord Blood as the Donor Source of our NK Cell Product Candidates

Cord blood is a recognized source of healthy donor cells for hematopoietic stem cell transplants and is readily available from multiple public banks in the United States and Europe. NK cells make up 5% to 15% of peripheral blood lymphocytes. Traditionally, peripheral blood has been used as the source for NK cells for therapeutic use. However, studies conducted by GC Cell have shown that NK cells derived from cord blood have a nearly ten-fold greater potential for expansion in our proprietary culture systems than those derived from peripheral blood, without premature exhaustion. The expression of receptors of interest on the surface of NK cells, such as those involved in the activation of NK cells on engagement of tumor cells, was seen to be more consistent donor-to-donor for cord blood NKs than peripheral-blood NK cells. Our manufacturing process activates the NK cells in cord blood in a donor-independent manner, resulting in a highly scaled, active and consistent NK cell product.

Selection of Optimal Genetic Characteristics in the Donor Cord Blood Units

We pre-screen banked cord blood units for both the KIR-B haplotype and high-affinity variant of the CD16 receptor which are drivers of NK cell activity:

▪**KIR-B haplotype selection:** We base our product candidates on cord blood units encoding KIR-B alleles of the KIR receptor family. It has been reported that KIR-B haplotype NK cells have more activating receptors than KIR-A. It has also been reported that acute myeloid leukemia patients receiving allogeneic transplants from homozygous KIR-B donors have significantly decreased relapse rates and increased disease-free survival than those receiving transplants from KIR-A donors.

▪**High-Affinity CD16 158V/V selection:** We select cord blood units that have a variant of CD16 known as 158 V/V, which has been shown to lead to increased ADCC activity. In a clinical trial of rituximab, an anti-CD20 mAb, follicular lymphoma patients with the CD16 genotype encoding the 158 V/V allele had a significantly higher response rate compared to those with other CD16 genotypes.

Approximately 15% of cord blood units have the characteristics above. Following pre-selection, we ship the cord blood units to our manufacturing facility where they are held in cryostorage. We believe that the availability, quality, ability to prescreen and ease of logistics of cord blood make it the optimal donor cell source for our proprietary manufacturing process.

Established and Highly Scaled Proprietary Manufacturing Process

We are leveraging a manufacturing process designed to be cGMP-compliant and potentially optimized for highly scaled expansion of the NK cells from a cord blood unit using a proprietary culture system. The NK cells from selected cord blood units are expanded using a proprietary engineered feeder (eFeeder) cell culturing process. The eFeeder cells are engineered to express a combination of factors on their surface, which enhance the activation and expansion of NK cells from the cord blood unit. The eFeeder cells are manufactured in-house, irradiated and do not persist in the final product. This process has been developed to produce large numbers of mature and highly active NK and CAR-NK cells while avoiding overstimulation, which has been shown to lead to cellular senescence.

The NK cell expansion process consists of the following steps:

▪**MCB production:** The cord blood unit is thawed and depleted of T-cells before culturing with the eFeeder cells, resulting in a significant expansion and enrichment of NK cells. For CAR-NK product candidates, a lentivirus vector encoding the specific CAR construct and IL-15 can be introduced at this stage. This results in the generation of cryopreserved MCB which is then stored in vials. MCB samples are assessed for quality against qualified release specifications before use in the second expansion stage. For AlloNK, we routinely produce 50-80 vials of MCB from each cord blood unit. We have produced multiple MCBs from different donor cord blood units for each product candidate.

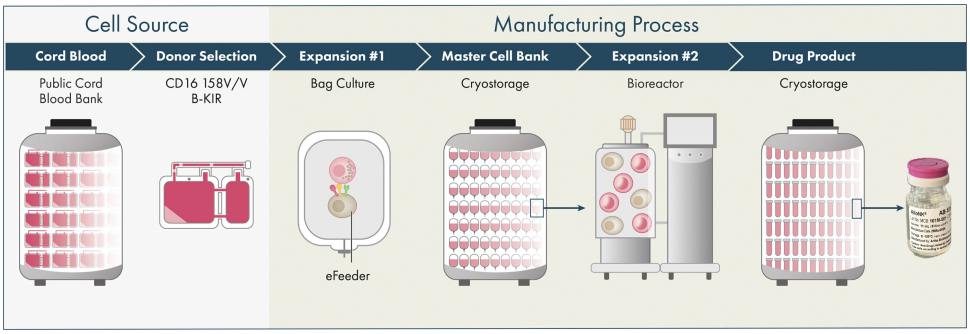
▪**Drug product production:** A single vial of MCB is used to seed a second expansion step. This takes place in a 50-liter, single-use bioreactor and results in highly activate, pure NK cells. The NK cells are harvested, vialed and cryopreserved. For AlloNK, we routinely produce >80 vials of one billion NK cells per vial for clinical use from each drug product batch. We have multiple bioreactors installed at both our San Diego facility and GC Cell and have capacity to produce up to 100 batches per year across both sites. Samples of drug product from each batch are tested using qualified assays prior to release for clinical use.

▪**Product characterization:** Our highly scaled and reproducible process for generating cord blood-derived NK and CAR-NK cells has yielded drug product that has consistently been observed to meet release specifications across manufacturing runs. For AlloNK, we and GC Cell have produced over 50 batches of drug product which passed all of our release criteria including criteria for purity, identity and functional activity.

▪**Effective cryopreservation:** The effective long-term storage of cells while retaining product viability and potency is an essential step in providing off-the-shelf NK and CAR-NK cell therapies. The final step in the manufacturing process is cryopreservation. We believe that the ability to effectively cryopreserve our NK and CAR-NK cell therapy product candidates is a key differentiator for our

platform and is essential to providing off-the-shelf products that can be shipped around the world and be available on demand for single or repeat patient dosing. Historically, NK cells have been reported to be highly sensitive to the stresses of a freeze-thaw cycle, and cryopreservation of NK cells has therefore been more challenging than T-cells. Our proprietary cryopreservation process uses methods that have consistently demonstrated >90% viability of our NK cells upon thawing, with no significant differences in NK cell activity or expression of cytokines, such as interferon-γ and TNFα.

For AlloNK, at the current scale, each cord blood unit is expanded to yield 50 to 80 cryopreserved MCB units. In turn, each MCB unit is further expanded to yield 80 to 100+ one billion-cell drug product vials. The demonstrated expansion from a single cord blood unit is therefore over 4,000 one billion-cell vials which are enough to treat over 250 to 1,000 autoimmune patients assuming one billion to four billion AlloNK cells per dose and three doses for a treatment regimen of an aggregate of three billion to twelve billion AlloNK cells total per patient with autoimmune disease. To date, we and GC Cell have produced over 50 clinical batches of AlloNK, producing thousands of AlloNK vials at one billion cells per vial, and have performed release testing on drug product derived from eight different donors. We have demonstrated both batch-to-batch and donor-to-donor consistency.



Our Manufacturing Process Can Generate Thousands of Doses of AlloNK from a Single Cord Blood Unit

We are conducting an ongoing product stability study to assess the shelf-life of our NK cell product candidates. We have tested each batch of AlloNK for cell viability, identity, purity, sterility and potency. To date, we have demonstrated stable results at 48 months. Our cryopreservation process was designed using an infusion-ready media not only to ensure that the thawed cells retain high and consistent activity, but also to enable a simple thawing process in which the drug product does not require any further processing before administration.

Our Facility

In addition to the research and manufacturing capabilities at GC Cell's headquarters in Korea, we have established full development and manufacturing facilities in San Diego, California. We have built a new 52,000-square-foot corporate headquarters, which includes research and process development laboratories, and have recruited a team of cell therapy experts driving discovery research, preclinical development, translational science, process and analytical development, and cell therapy manufacturing Our headquarters also includes a 9,000 square-foot purpose-built cGMP manufacturing center to support NK and CAR-NK cell production for our pipeline development and clinical trial supply. This new facility capacity is in addition to on-going manufacturing in Korea.

Our scaled manufacturing process established at GC Cell over more than ten years has enabled us to design an efficient layout for our San Diego manufacturing center that is cGMP compliant. Our facility comprises multiple production suites, a MCB / virus suite and a suite devoted to product fill-finish and cryopreservation. Each of the three 50L bioreactor suites dedicated to drug product production have the capacity to run 20 batches per year. Given drug product batches can yield more than 80-100 AlloNK vials with one billion NK cells each, our facility has the capacity to generate over 5,000 one billion NK cell vials per year.

Released finished product is stored off site at a third-party logistics vendor, as is currently the case for drug products manufactured for us by GC Cell. We intend to use our facility to enable new pipeline program research, development and manufacturing, to further optimize the AlloNK manufacturing process and produce AlloNK for current and future clinical trials and to supply any potential commercial launch.

Competition

The biopharmaceutical industry in general, and the cell therapy field in particular, is characterized by rapidly advancing and changing technologies, intense competition and a strong emphasis on intellectual property. We face substantial and increasing competition from large and specialty biopharmaceutical companies, as well as public and private medical research institutions and governmental agencies. Competitors may compete with us in hiring scientific and management personnel, establishing clinical study sites, recruiting patients to participate in clinical trials and acquiring technologies complementary to, or necessary for, our programs.

Our known biopharmaceutical competitors that are developing allogeneic CAR-NK or CAR-T cell therapies or T-cell engaging bispecific antibodies include, but may not be limited to, the following: Adicet Bio, Inc., Allogene Therapeutics, Inc., Amgen Inc., Autolus Therapeutics plc, Bristol-Myers Squibb Co, Cabaletta Bio, Inc., Candid Therapeutics, Inc., Caribou Biosciences, Inc., Cartesian Therapeutics, Inc., Century Therapeutics, Inc., Cullinan Therapeutics Inc., Fate Therapeutics, Inc., Galapagos NV, Gilead Sciences, Inc., Gracell Biopharmaceuticals, Inc. (acquired by AstraZeneca), GSK plc, iCell Gene Therapeutics Inc., ImmPACT Bio USA, Inc. (acquired by Lyell Immunopharma, Inc.), ITabMed Co., Ltd., Johnson & Johnson, Kyverna Therapeutics, Inc., Luminary Therapeutics, Inc., Merck & Co., Inc., Nkarta, Inc., Novartis AG, Regeneron Pharmaceuticals, Inc., Roche, Sana Biotechnology, Inc., Sanofi, Shoreline Biosciences Inc., Synthekine Inc., Takeda Pharmaceuticals Company Limited, Wugen, Inc. and Xencor, Inc.

Many of our current or potential competitors have significantly greater financial, technical and human resources, as well as more expertise in research and development, manufacturing, preclinical testing, conducting clinical studies and trials and commercializing and marketing approved products, than us. Mergers and acquisitions in the biopharmaceutical industry may result in even greater resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, either alone or through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other comparable foreign regulatory authority approval for their products more rapidly than us, which could result in our competitors establishing a strong market position before we are able to enter the market. Key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, price and degree of reimbursement.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. Our commercial success depends in part on our ability to obtain intellectual property that protects our product candidates and combinations of our product candidates with other therapeutics. We seek to protect and enhance proprietary technology, inventions and improvements that are commercially important to the development of our business by seeking, maintaining and defending U.S. and foreign patent rights, whether developed internally or licensed from third parties.

We are actively building our intellectual property portfolio around our product candidates and our discovery programs, based on our own intellectual property and licensed intellectual property. One important step in building our current portfolio was executing the Core Agreement, described below, with GC Cell. The Core Agreement grants us an exclusive, royalty-bearing license, with the right to sublicense through multiple tiers, to certain intellectual property and technology owned or controlled by GC Cell relating to non-genetically modified and genetically modified NK cells, and culturing, engineering, and manufacturing thereof, to research, develop, manufacture, and commercialize NK cell pharmaceutical products anywhere in the world except for Asia, Australia

and New Zealand (the Artiva Territory). Applications to date have been filed in the United States, Europe, Canada and Israel. Further, we intend to file patent applications relating to new technologies we develop, either ourselves or with our strategic partners. We also intend to continue to identify and license patents that provide protection and serve as an optimal platform to enhance our intellectual property and technology base.

Our current intellectual property estate is designed to provide multiple layers of protection, including (1) patent rights directed to innovative manufacturing processes and methods for generating therapeutic NK cells; (2) patent rights covering constructs for use in our CAR-NK candidates; and (3) patent rights covering methods of treatment for therapeutic indications using NK cells.

Our current patent portfolio as of March 1, 2025, includes seven patent families licensed from GC Cell that primarily relate to innovative manufacturing processes and methods for generating therapeutic NK cells. These families disclose compositions and methods used in NK cell manufacturing processes, as well as resulting products and therapeutic compositions, along with methods of treating cancer using these products and therapeutic compositions.

Our current patent estate as of March 1, 2025, includes three patent families licensed from GC Cell, three patent families we co-own with GC Cell, and one patent family that we own covering constructs for use in our CAR-NK programs. Two of the families we license from GC Cell relate to particular CAR components. The first of these includes pending applications in the United States, Europe, and Canada, and any patents that issue from these pending applications are expected to expire in 2037, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees; the second of these includes a pending application in the United States, and any patents that issue from this pending application are expected to expire in 2042, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The third family we license from GC Cell relates to a novel anti-HER2 antibody or antigen-binding fragment and includes three issued U.S. patents and pending applications in the United States, Europe, Canada, and Israel. The issued U.S. patents are expected to expire in 2038, and any patents that issue from the pending patent applications in these licensed families are expected to expire between 2038 and 2041, without accounting for potentially available patent term adjustments or extensions and assuming payment of appropriate maintenance, renewal, annuity or other fees. Two of the families we co-own with GC Cell relate to cells and constructs encoding IL-15 and a CAR utilizing the novel anti-HER2 antigen binding fragment we license from GC Cell and methods of treatment using these cells and constructs. The first of these families includes pending applications in the United States, Europe, Israel, and Canada, and any patents that issue from these pending applications are expected to expire in 2042, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees; the second of these families includes pending applications in the United States, Thailand, Singapore, Israel, Indonesia, Europe, China, Canada, and Australia, and any patents that issue from these pending applications are expected to expire in 2043, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The third family we co-own with GC Cell relates to our anti-CD19 CAR-NK cell products and includes pending applications in the United States and Europe; any patents that issue from these pending applications are expected to expire in 2042, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The patent family that we own relates to a novel antibody or antigen binding fragment and includes a pending PCT application. Although no patents have yet issued from this owned patent family, we expect the term of any patents that may issue from the pending patent applications in this family to extend to at least 2043, without accounting for potentially available patent term adjustments or extensions and assuming payment of appropriate maintenance, renewal, annuity or other governmental fees.

Our current patent estate as of March 1, 2025, includes twelve patent families related to NK cells and to methods of treatment using NK cells in addition to a therapeutic antibody. The first family, which is co-owned by GC Cell and Incyte Corporation, relates to pharmaceutical combinations for treating tumors comprised of anti-CD19 antibody and NK cells. This family includes pending applications in Canada, Europe, Israel, the United States, Eurasia, Mexico, Ukraine, and South Africa; any patents that issue from these pending applications are expected to expire in 2039, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The second family, which we co-own with GC Cell, relates to the treatment of cancer with NK cells and a CD20 targeted antibody. This family includes pending applications in the United States and Europe; any patents that issue from these pending applications are expected to expire in 2041, without accounting for potentially available patent term adjustment or extensions, and assuming

payment of appropriate maintenance, renewal, annuity, or other fees. The third and fourth families, which we own, relate to the treatment of autoimmune indications with NK cells and therapeutic antibodies and includes a pending PCT application and a pending U.S. provisional application; any patents that issue from these pending applications are expected to expire in 2044 and 2045, respectively, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The fifth and sixth families, which we own, relate to methods of treatment using NK cells in combination with other therapeutics. The fourth family includes a pending U.S. provisional application; any patents that issue from applications that claim priority to this provisional application are expected to expire in 2044, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The fifth family includes a pending PCT application; any patents that issue from this pending application are expected to expire in 2044, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The seventh family, which we own, relates to engineered NK cells and methods of treatment and includes a pending U.S. provisional application; any patents that issue from applications that claim priority to this provisional application expected to expire in 2045, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The other five patent families, which we co-own with GC Cell, relate to NK cells and to additional combinations of NK cells and therapeutic antibodies directed to various targets. Of these, the first family includes pending applications in the United States, Europe, Canada, and Israel; any patents that issue from these pending applications are expected to expire in 2041, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees. The remaining families each include pending applications in the United States, Europe, Australia, China, Japan, and Korea; any patents that issue from these pending applications are expected to expire in 2042, without accounting for potentially available patent term adjustment or extensions, and assuming payment of appropriate maintenance, renewal, annuity, or other fees.

Our current patent estate as of March,1 2025, also includes a patent family co-owned by us, Affimed GmbH and GC Cell related to therapeutic compositions and methods of treating cancer using NK cells in combination with one of Affimed's innate cell engagers. This family includes pending applications in the United States, Australia, Canada, China, Europe, Israel, India, Japan, and Korea. We expect the term of any patents that issue from the pending patent applications in this family to extend until at least 2042, without accounting for potentially available patent term adjustment or extension and assuming payment of appropriate maintenance, renewal, annuity or other governmental fees.

With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (USPTO) in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension is calculated based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a biologics license application (BLA), we expect to apply for patent term extensions for patents covering our product candidates and their methods of use.

In addition to patent protection, we also seek to rely on regulatory protection and exclusivities. For instance, we intend to rely on the 12-year period for marketing exclusivity in the United States, and similar marketing exclusivities in other countries, to prevent competitors from obtaining regulatory approval for our products.

We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and invention assignment agreements to develop and maintain our proprietary position. The confidentiality agreements are designed to protect our proprietary information and the invention assignment agreements are designed to grant us ownership of technologies that are developed for us by our employees, consultants, or other third parties. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights.

Collaboration and License Agreements

GC Cell and Related Agreements

We have entered into several agreements with GC Cell and related entities concerning our platform NK cell technology and manufacturing of our core products, as described below.

Option and License Agreement with GC Cell

In September 2019, we entered into an option and license agreement with GC Cell, as amended in June 2020 and February 2022 (Core Agreement). Under the Core Agreement, GC Cell granted us an exclusive, royalty-bearing license, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell relating to non-genetically modified and genetically modified NK cells, and culturing, engineering, manufacturing thereof, to research, develop, manufacture and commercialize NK cell pharmaceutical products in the Artiva Territory. GC Cell retained rights under the license to allow it and its affiliates to perform obligations under the Core Agreement and other agreements between us and them.

Under the Core Agreement, GC Cell agreed to conduct a discovery, research, preclinical development and manufacturing program under a plan approved by a Joint Research Steering Committee (JSC), to generate and identify product candidates for nomination as option candidates. GC Cell will bear all costs for its work under the R&D Plan, except that we will bear all costs for completing IND-enabling activities performed by GC Cell on behalf of us, other than certain efficacy studies.

For each product candidate determined by the JSC to be an option candidate, we have an exclusive option under the Core Agreement to obtain an exclusive, sublicensable license to research, develop, manufacture and commercialize such candidate in the Artiva Territory for any therapeutic, prophylactic or diagnostic uses in humans, on economic terms to be determined in good faith by the parties. GC Cell retains exclusive rights to the licensed technology in Asia, Australia and New Zealand, though we have the right to request, and GC Cell has agreed to consider in good faith, inclusion of Australia, New Zealand and/or specific countries in Asia in the Artiva Territory on a product-by-product basis. If we elect not to exercise the option with respect to a particular option candidate, GC Cell retains the right to continue development of such candidate. To-date, we have exercised our rights to license four option candidates, including AlloNK (AB-101), AB-201 and AB-205.

We have control over and will bear the costs of the development, regulatory, manufacturing and commercialization activities relating to the option candidates for which we have exercised our option, each a licensed product. Accordingly, we have certain diligence obligations and must use commercially reasonable efforts to develop and seek regulatory approval for each licensed product in at least one indication in the United States and the EU, and following regulatory approval in a country, to commercialize such licensed product in at least one indication in such country. The Core Agreement provides that we have the right to engage GC Cell or its appropriate

affiliate to provide research and manufacturing services for the licensed products being developed by us in the Artiva Territory under separately executed service agreements.

Under the Core Agreement, we are obligated to pay a low single-digit percentage royalty on net sales of any licensed products, the manufacture, use or sale of which is claimed by or uses any Core IP. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed product and continuing until the later of (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. We also have the exclusive option to extend our license to the Core IP to be worldwide with respect to products originated from us in exchange for a specified increase in the applicable royalty. GC Cell is also obligated to pay us a royalty at a rate equal to 50% of the royalty payable by us for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property.

The Core Agreement will remain in effect until the expiration of the last-to-expire royalty payment obligations. The last to expire patents (or any patents that issue from pending applications) underlying the royalty payment obligations under the Core Agreement are currently expected to expire by 2042, without accounting for potentially available patent term extensions or adjustments. We have the right to terminate the Core Agreement for any reason upon 90 days' written notice. Either party may terminate the Core Agreement upon the other party's uncured material breach, bankruptcy or insolvency. Upon termination of the Core Agreement for any reason other than uncured material breach by GC Cell, we must (i) assign and transfer all regulatory materials and approvals relating to any licensed product to GC Cell, and (ii) grant GC Cell a right of reference and use to all pre-clinical and clinical data relating to any licensed product, except that both (i) and (ii) only apply to licensed products that were developed at least in part by GC Cell, or were developed by a third party, and are claimed by or use licensed GC Cell technology. If the Core Agreement is terminated by GC Cell due to an uncured material breach, bankruptcy or insolvency, sublicensees may receive a direct license from GC Cell.

AB-101 Selected Product License Agreement

In November 2019, we entered into a license agreement with GC Cell for our AB-101 product candidate, as amended in February 2022 (the AB-101 Agreement). AB-101 is the first product for which we exercised our option under the Core Agreement. Under the AB-101 Agreement, GC Cell granted us an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture and commercialize AB-101.

Under the AB-101 Agreement, we are obligated to pay tiered royalties in the low-mid to high single-digit percentage range on annual net sales of any licensed AB-101 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-101 product and continuing until the later of (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. We are also obligated to make milestone payments to GC Cell of (i) up to $22.0 million upon the first achievement of certain development milestones, and (ii) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay us a royalty at a rate equal to 50% of the royalty payable by us for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-101 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property.

The AB-101 Agreement will remain in effect until the expiration of the last-to-expire royalty payment obligations. The last to expire patents (or any patents that issue from pending applications) underlying the royalty payment obligations under the AB-101 Agreement for AB-101 are currently expected to expire by 2042, without accounting for potentially available patent term extensions or adjustments. We have the right to terminate the AB-101 Agreement for any reason upon 90 days' written notice. Either party may terminate the AB-101 Agreement upon the other party's uncured material breach, bankruptcy or insolvency. Upon termination of the AB-101 Agreement for any reason other than uncured material breach by GC Cell, we must (i) assign and transfer all

regulatory materials and approvals relating to AB-101 to GC Cell, and (ii) grant GC Cell a right of reference and use to all pre-clinical and clinical data relating to AB-101.

AB-201 Selected Product License Agreement

In October 2020, we entered into a license agreement with GC Cell for our AB-201 product candidate, as amended in February 2022 and September 2023 (the AB-201 Agreement). AB-201 is the second product for which we exercised our option under the Core Agreement. Under the AB-201 Agreement, GC Cell granted us an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture and commercialize AB-201.

Under the AB-201 Agreement, we paid a one-time, upfront fee of $0.3 million as reimbursement of certain costs previously incurred by GC Cell relating to AB-201. We are obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-201 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-201 product and continuing until the later of (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. We are also obligated to make milestone payments to GC Cell of (i) up to $25.0 million upon the first achievement of certain development milestones, and (ii) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay us a royalty at a rate equal to 50% of the royalty payable by us for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-201 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property. Further, in consideration of a grant-back license and right of reference to certain intellectual property rights and regulatory filings owned or controlled by us in the Artiva Territory for the exploitation of the AB-201 product outside the Artiva Territory, GC Cell is further obligated to pay us a low single-digit royalty on net sales outside the Artiva Territory of any licensed AB-201 product, as well as up to $1.8 million upon the first achievement of certain development milestones.

The AB-201 Agreement will remain in effect until the expiration of the last-to-expire royalty payment obligations. The last to expire patents (or any patents that issue from pending applications) underlying the payment obligations under the AB-201 Agreement are currently expected to expire by 2043, without accounting for potentially available patent term extensions or adjustments. We have the right to terminate the AB-201 Agreement for any reason upon 90 days' written notice. Either party may terminate the AB-201 Agreement upon the other party's uncured material breach, bankruptcy or insolvency. On termination of the AB-201 Agreement for any reason other than uncured material breach by GC Cell, we must (i) assign and transfer all regulatory materials and approvals relating to AB-201 to GC Cell, and (ii) grant GC Cell a right of reference and use to all pre-clinical and clinical data relating to AB-201.

AB-205 Selected Product License Agreement

In December 2022, we entered into a license agreement with GC Cell for our AB-205 product candidate (the AB-205 Agreement). AB-205 is the fourth product for which we exercised our option under the Core Agreement. Under the AB-205 Agreement, GC Cell granted us an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture and commercialize AB-205.

Under the AB-205 Agreement, we paid to GC Cell a one-time, upfront payment of $1.0 million, and we are obligated to make a payment of $2.5 million to GC Cell after we notify GC Cell that we opt to proceed to clinical development with an AB-205 product. We are also obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-205 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-205 product and continuing until the later of (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for such licensed product in such country; and (iii) the tenth anniversary of the first commercial sale of

such licensed product in such country. We are also obligated to make milestone payments to GC Cell of (i) up to $29.5 million upon the first achievement of certain development milestones, plus cost sharing of certain development costs incurred by GC Cell, and (ii) up to $28.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay us a royalty at a rate equal to 50% of the royalty payable by us for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-205 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property.

The AB-205 Agreement will remain in effect until the expiration of the last-to-expire royalty payment obligations. The last to expire patents (or any patents that issue from pending applications) underlying the royalty payment obligations under the AB-205 Agreement are currently expected to expire by 2043, without accounting for potentially available patent term extensions or adjustments. We have the right to terminate the AB-205 Agreement for any reason upon 90 days' written notice. Either party may terminate the AB-205 Agreement upon the other party's uncured material breach, bankruptcy or insolvency. Further, GC Cell may terminate the AB-205 Agreement if we do not elect to proceed with clinical development of the AB-205 Product after receipt of certain clinical data provided by GC Cell. Upon termination of the AB-205 Agreement for any reason other than uncured material breach by GC Cell, we must (i) assign and transfer all regulatory materials and approvals relating to AB-205 to GC Cell, and (ii) grant GC Cell a right of reference and use to all pre-clinical and clinical data relating to AB-205.

Research Services Agreement with GC Cell

As contemplated by the Core Agreement, in August 2020 we entered into the GC Cell Research Services Agreement, as amended in February 2022, under which GC Cell agreed to provide research services in support of the research and development of one or more of the products we have licensed from GC Cell. The GC Cell Research Services Agreement provides that the parties will agree to specific projects as work orders under the GC Cell Research Services Agreement. Each work order shall set forth, upon terms mutually agreeable to GC Cell and us, the specific services to be performed by GC Cell, the timeline and schedule for the performance of the services and the compensation to be paid by us to GC Cell for the provision of such services, as well as any other relevant terms and conditions. Unless otherwise agreed by the parties in a work order, GC Cell will own all intellectual property generated in the course of its provision of services under the Agreement, and all such intellectual property, to the extent related to or arising from the licensed technology under the Core Agreement and selected product license agreements, including the AB-101 Agreement and the AB-201 Agreement, will be included in the licenses granted to us thereunder.

The GC Cell Research Services Agreement terminates on the five-year anniversary of its execution, except that GC Cell is obligated to complete any work orders that remain open at the time the agreement terminates. Both parties have the right to terminate the GC Cell Research Services Agreement for any reason upon 90 days' written notice, though if GC Cell terminates the GC Cell Research Services Agreement without cause, then at our option the termination shall not be effective until the later of (a) the end of the 90-day notice period, or (b) the date on which the services provided under the open work order have been completed. Either party may terminate the GC Cell Research Services Agreement or any work order upon thirty (30) days' written notice in the event of an uncured material breach. Either party may also terminate the GC Cell Research Services Agreement immediately in writing if the other party or its affiliates breaches the requirement that no individuals debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, or comparable applicable laws, may perform the services or use the data and intellectual property hereunder.

Master Manufacturing Agreement with GC Cell

In March 2020, we entered into a Master Agreement for Manufacturing Services (the Manufacturing Agreement) with GC Cell, formerly GC Lab Cell Corporation, under which GC Cell agreed to manufacture specified products under individual work orders for use in our Phase 1 and Phase 2 clinical trials. Each work order will contain an estimated budget of service fees and out-of-pocket costs to be incurred in the performance of services under the agreement and the work order, as well as additional terms and conditions relating to the estimated budget. We will own all results and data generated by GC Cell under the Manufacturing Agreement. GC Cell may not subcontract its performance, even to affiliates, without our written consent.

Under the Manufacturing Agreement, we granted GC Cell a limited non-exclusive, non-transferable, non-sublicensable, revocable, royalty-free license to our pre-existing intellectual property that is necessary and useful to manufacture products for us. Any intellectual property generated in the course of the manufacturing will be owned by us. GC Cell granted us a limited worldwide, royalty-free, fully paid, non-exclusive license, including the right to sublicense through multiple tiers, to GC Cell background technology and improvements thereof used to manufacture products under the agreement. These licenses survive termination of the Manufacturing Agreement.

The Manufacturing Agreement expires on the five-year anniversary of its execution, unless terminated earlier or extended by the parties in writing. Under the terms of the Manufacturing Agreement, as amended in July 2020, we have the right to terminate the Manufacturing Agreement at any time and for any reason upon six (6) months written notice. We also have the right to terminate any open work order at any time and for any reason upon sixty (60) days' written notice. Either party may terminate the Manufacturing Agreement or any work order upon thirty (30) days' written notice in the event of an uncured material breach. GC Cell may terminate any work order on sixty (60) days' prior written notice if GC Cell reasonably concludes that it is not technically or scientifically feasible to deliver the services contemplated by such work order despite applying its commercially reasonable efforts, but only if (i) such non-feasibility is not caused by GC Cell and is outside of GC Cell's reasonable control and (ii) the parties are unable to resolve such scientific or technical issues within a sixty (60) day period.

Affimed Collaboration Agreement

In November 2022, we entered into a collaboration agreement (the Affimed Collaboration Agreement) with Affimed, as amended in November 2022 and June 2023. The collaboration is focused on the clinical development and commercialization of a combination therapy comprising (i) Affimed's product acimtamig and (ii) our product AlloNK in the United States and certain other countries that we and Affimed may agree to include, excluding specified Asia Pacific region countries (the Territory) for any and all uses in humans and animals, with an initial focus on the treatment of CD30+ Hodgkin Lymphoma and Peripheral T-Cell Lymphoma and other indications that may be included in a development plan.

Under the Affimed Collaboration Agreement, we granted Affimed, under certain intellectual property and technology owned or controlled by us relating to AlloNK, (a) an exclusive, non-transferable (except to affiliates and successors in interest), royalty-free and non-sublicensable (except to affiliates and subcontractors) license to use AlloNK to clinically develop the combination therapy in the Territory in accordance with a development plan, and (b) a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free and non-sublicensable (with certain exceptions) license to promote the combination therapy in the Territory. Affimed granted us a non-exclusive, royalty-free, non-transferable (except to affiliates and successors in interest) and non-sublicensable (except to affiliates and subcontractors) license under certain intellectual property and technology owned or controlled by Affimed relating to acimtamig to use acimtamig to clinically develop the combination therapy in the Territory in accordance with a development plan. Affimed will be primarily responsible for the development of the combination therapy, the conduct of the relevant clinical trials and the preparation and filing of regulatory materials during the clinical development. We will support Affimed in the development, in particular through the supply of AlloNK and our IL-2 product to be used in the clinical trials. Affimed will have the sole right and responsibility to promote the combination therapy according to a jointly aligned promotion plan.

During the term of the Affimed Collaboration Agreement, and subject to certain exceptions, neither party nor its affiliates is permitted to clinically develop or commercialize any other product or therapy comprising its product (i.e., acimtamig for Affimed and AlloNK for us) in the Territory, whether as a monotherapy or part of a combination therapy, for any indication which is included in the then applicable development plan and for which we and Affimed have agreed to file an IND. In addition, during the term of Affimed Collaboration Agreement, Affimed may not clinically develop or commercialize any product or therapy comprising its acimtamig with other NK cells (except for indications which Affimed has proposed and we have rejected to include in the development plan or rejected to file an IND), and we may not clinically develop or commercialize any product that directly and specifically binds to CD30 without any known off-target binding that is pre-clinically or clinically relevant in the Territory (except for indications which we have proposed and Affimed has rejected to include in the development plan or rejected to file an IND).

Affimed is responsible for all costs associated with the development of the combination therapy (including all clinical trial costs), except that we and Affimed shall each bear 50% of the costs and expenses incurred in connection with the performance of any confirmatory clinical trial required by the FDA for the combination therapy. We are solely responsible for all costs incurred by us for the supply of AlloNK and our IL-2 product used in the combination therapy clinical trials and for the conduct of certain development activities assigned to us under the development plan. In addition, we and Affimed have agreed to make payments to each other to achieve a proportion of 67%/33% (Affimed/us) of revenues generated by both parties from commercial sales of each party's product as part of the combination therapy, with such payment obligations commencing on the first commercial sale of a combination product by us or Affimed and expiring on a country-by-country basis upon the earlier of (1) biosimilar market entry in such country and (2) the later of (x) the expiration of all collaboration patents in such country and (y) the expiration of regulatory data exclusivity of acimtamig or AlloNK in such country.

Unless earlier terminated, the Affimed Collaboration Agreement will expire when there are no remaining payment obligations by either party in the Territory. Either party may terminate the Affimed Collaboration Agreement in its entirety for any uncured material breach by the other party or upon the other party's insolvency, subject to certain notice and cure periods. In addition, Affimed may terminate the Affimed Collaboration Agreement if our ongoing clinical trial of AlloNK fails to meet certain specified success criteria set forth in the clinical trial protocol, subject to a certain notice and cure period.

We or Affimed may (during certain specified time windows during the clinical development phase) opt out of the further development and promotion of the combination therapy. If a party opts out, the other party may either terminate the Affimed Collaboration Agreement or elect to continue the development and promotion of the combination therapy, in which case the opting-out party is required to provide certain continued support activities (e.g., supply of its product), and the revenue ratio applicable to each party will be adjusted accordingly. In addition, if Affimed opts out and we elect to continue, we are required to pay Affimed a portion of its costs incurred before its opt-out, unless Affimed opts out after a change of control of Affimed.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of any of our approved products. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

Government Regulation and Product Approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our cell products will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell- or tissue-based products 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. Our products are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

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 product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory authorities before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union (EU) 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 (FDCA), the Public Health Service Act (PHSA) and their implementing 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 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 practices (GLPs) 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 (IRB) or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs), and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (GTPs), for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials

may not recommence without FDA authorization and then only under terms authorized by the FDA. 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 involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. 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 that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Certain clinical trials involving human gene transfer research also must be overseen by an Institutional Biosafety Committee, a standing committee established specifically to provide peer review of the safety of research plans, procedures, personnel training and environmental risks of work involving recombinant DNA molecules. IBCs are typically assigned certain review responsibilities relating to the use of recombinant DNA molecules, including reviewing potential environmental risks, assessing containment levels, and evaluating the adequacy of facilities, personnel training and compliance with the NIH Guidelines. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory authorities require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor

also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

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 patients 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 product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The 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 (PDUFA), as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS), is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines

by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required. Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue and cellular and tissue based products (HCT/Ps), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted In compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP 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.

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

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act (PREA), as amended, 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 FDCA requires that a sponsor of a biological product or drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit a pediatric study plan to the FDA not later than 60 days after the end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The FDA may grant deferrals for submission of data or full or partial waivers. Generally, 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).

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the 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 a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

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

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product, submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review.

Additionally, depending on the design of the applicable clinical studies, a product may be eligible for accelerated approval. In particular, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies and may require such confirmatory studies to be underway prior to granting any accelerated approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In addition, breakthrough therapy designation is intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive

communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may submit sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same product if relevant criteria are met. If a product is designated as breakthrough therapy, FDA will expedite the development and review of such product. Fast Track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any 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 a physician may prescribe a legally available product for an off-label use, if the physicians deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including administrative, civil and criminal sanctions.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products 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 and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. 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, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act (BPCIA), amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for 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 product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, either the referral of an individual for, or the purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Additionally, 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. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a

cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

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

The federal civil False Claims Act (FCA) prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government in order to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. Pharmaceutical and other healthcare companies are being investigated or, in the past, have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, pharmaceutical and other healthcare companies also have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. Moreover, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations, imposes requirements on certain types of individuals and entities, including covered entities, for example, certain healthcare providers, health plans and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, relating to the privacy, security and transmission of individually identifiable health information. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar fraud and abuse statutes or regulations similar to the aforementioned federal laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such

manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states and local jurisdictions have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Data Privacy and Security Laws

We are and may in the future become subject to numerous state, federal and foreign laws, regulations and standards that govern the collection, use, access to, confidentiality and security of health-related and other personal information. In the United States, such obligations may include, without limitation various federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (the CCPA) applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages.

Outside the United States, under foreign laws, such as the General Data Protection Regulation, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the European Union's General Data Protection Regulation 2016/679 (EU GDPR), 17.5 million pounds sterling under the EU GDPR as it forms part of United Kingdom law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. See the section titled "Risk Factors – Risks Related to Government Regulation" for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and certain markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. No uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often time-consuming and costly.

In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or from establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, any companion diagnostic test that we develop will be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we seek for our product candidates, if approved.

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

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of

containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid drug rebate program are calculated, 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. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new Patient-Centered Outcomes Research Institute. Since its enactment, there have been executive, judicial and political challenges and amendments to certain aspects of the Affordable Care Act.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions to Medicare payments to providers, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments to the statute will stay in effect through 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, which was previously capped at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, which began on January 1, 2024.

Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. It is possible that other healthcare reform measures may be adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal 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. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law which, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law (the "Medicare Drug Price Negotiation Program"), and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Foreign Corrupt Practices Act

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

Additional Regulation

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

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

For other countries outside of the EU, 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 country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union, or EU are subject to significant regulatory controls. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 (CTR), which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 (CTD).

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System (CTIS); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference EU Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned EU Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent

authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials, including ATMPs, must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

EU Review and approval process of medicinal products

In the EU, medicinal products can only be commercialized after a related marketing authorization (MA) has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application (MAA) either under a centralized procedure administered by the European Medicines Agency (EMA), or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (CHMP) conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures—Human (CMDh) for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA 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 EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines (PRIME) scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product 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. 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 potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Advanced Therapy Medicinal Products in the EU

ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. The grant of marketing authorization in the EU for products containing viable human tissues or cells such as gene therapy medicinal products is governed by Regulation (EC) No. 1394/2007 on ATMPs, read in combination with Directive (EC) No. 2001/83 of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation (EC) No. 1394/2007 establishes specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the EMA which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Products made from substances of human origin must also comply with Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application. This Regulation describes the conditions and quality requirements which must be applied when sourcing the substances of human origin intended for manufacturing of such medicinal products and removed divergences between EU Member States that were present under the (now repealed) Directive (EC) No. 2004/23.

Pediatric Development in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate (SPC), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Manufacturing Regulation in the EU

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity in the EU

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the

innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Orphan Designation in the EU

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than five in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the ten year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-authorization Requirements in the EU

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MAAs must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristic (SmPC), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Pricing, Coverage and Reimbursement in the EU

In the EU, pricing and reimbursement schemes vary widely from country to country. Some EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA, was adopted in the EU. This Regulation, which entered into application on January 12, 2025 and has a phased implementation, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Corporate Philanthropy

We have joined the Pledge 1% Movement, a global movement that supports the integration of philanthropy into corporate culture by inspiring companies to donate 1% of product, equity, profit, or employee time to causes of their choice, demonstrating our commitment to philanthropic leadership, particularly in the biotechnology sector. As such, in July 2021, our board of directors approved the reservation of up to 84,556 shares of our common stock (which was approximately 1.0% of our fully-diluted capitalization as of that date) that we may issue to or for the benefit of a charitable foundation established by us or other appropriate charitable recipients pursuant to our Pledge 1% Movement commitment. The common stock will be donated in equal installments over five years following this offering or in full upon a sale of our company, in each case first subject to certain per-share valuation thresholds for our common stock. We have not yet issued any such reserved common stock. If any reserved common stock is issued pursuant to our Pledge 1% Movement commitment, we may incur a non-cash expense in the quarter that we issue such shares equal to the fair value of the shares of our common stock issued. Such donation of shares may also dilute our stockholders' ownership of our common stock. Pursuant to this pledge, we plan to implement programs to encourage our employees to donate 1% of their time to charitable causes.

Facilities

Our principal office is located at 5505 Morehouse Drive, Suite 100, San Diego, California 92121, where we lease 51,621 square feet of space to house our principal office, research and process development laboratories and a cGMP manufacturing center to support our pipeline development and clinical trial supply. This lease will expire in 2029, subject to our option to an additional five-year term. We also have a lease agreement for an additional 13,405 square feet of office space in San Diego, California. We lease this space under a lease that terminates in June 2025. In addition, we have entered into a temporary license agreement for our occupation and use of an additional 11,960 square feet of office and laboratory space in San Diego, California. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Employees and Human Capital Resources

As of December 31, 2024, we had 89 full-time employees, 18 of whom held an M.D., Pharm.D. or Ph.D. degree and all of whom are engaged in research and development activities, operations, finance and administration. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our 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.

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.

Corporate Information

We were incorporated under the laws of the State of Delaware on February 14, 2019. Our principal executive offices are located at 5505 Morehouse Drive, Suite 100, San Diego, California, and our telephone number is (858) 267-4467. Our corporate website address is www.artivabio.com. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Annual Report on Form 10-K.

All brand names or trademarks appearing in this Annual Report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this Annual Report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act are available on our website, free of charge, as soon as reasonably practicable after the reports are electronically filed or furnished to the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information that we file with the SEC electronically. We intend to announce material information to the public through filings with the SEC, the investor relations page on our website, which is located at www.artivabio.com, press releases, public conference calls, and public webcasts.

The information disclosed through the foregoing channels could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels. The information we post through these channels is not a part of this Annual Report. Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.

Item 1A. Risk Factors

You should carefully consider the risks and uncertainties described below, as well as the other information in this Annual Report on Form 10-K and in our other public filings, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and in our other public filings, which could materially affect our business, financial condition or future results. The risks described below are not the only risks that we face. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and prospects.

We may disclose changes to risk factors or additional risk factors from time to time in our future filings with the SEC.

Risks Related to Our Limited Operating History, Financial Position and Need for Additional Capital

We have a limited operating history, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company with a limited operating history. We were incorporated in February 2019 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, licensing key intellectual property rights, conducting research and development of our product candidates ourselves and with collaborators, collaborating on scale-up of product candidate manufacturing, establishing cold chain delivery logistics and preparing for and conducting our ongoing and planned preclinical studies and clinical trials.

AlloNK, our lead product candidate, is in early clinical development and our other product candidates and programs are in preclinical development or discovery stages. We have not yet demonstrated an ability to successfully complete a clinical program, including large-scale, pivotal clinical trials, obtaining marketing approval, manufacturing product at a commercial scale, or arranging for a third party to do so on our behalf, or conducting sales and marketing activities necessary for successful product commercialization. This may make it difficult to evaluate the success of our business to date and assess our future viability.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and the significant risk that product candidates will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable. For the years ended December 31, 2024 and 2023, our net losses were $65.4 million and $28.7 million, respectively. As of December 31, 2024, we had an accumulated deficit of $246.7 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and additional operating losses for the foreseeable future as we seek to advance our product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, complete clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate any revenue from the commercialization of any approved products or achieve or maintain profitability. Our expenses will also increase substantially as we operate as a public company and add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

Before we generate any revenue from product sales, each of our product candidates will require additional preclinical and/or clinical development, potential regulatory approval in multiple jurisdictions, manufacturing, building of a commercial organization, substantial investment and significant marketing efforts. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency (EMA), the competent authorities of individual European Union (EU) Member States or comparable foreign regulatory authorities to perform preclinical studies and clinical trials in addition to those that we currently anticipate, and/or to modify any of our manufacturing processes or make other changes to our product candidates or development programs. As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance. If we are unable to develop and commercialize one or more of our product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our securities will be adversely affected.

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

The development of biopharmaceutical product candidates is capital-intensive. We expect to spend substantial amounts to advance our product candidates into clinical development and to complete the clinical development of, seek regulatory approvals for and commercialize our product candidates, if approved. We will require additional capital, which we may raise through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of our product candidates. Furthermore, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when

needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs.

Our operations have consumed significant amounts of cash since inception. As of December 31, 2024, our cash, cash equivalents and investments were $185.4 million. Based on our current cash, cash equivalents and investments, we estimate that our funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least through the end of 2026. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

•the type, number, scope, progress, expansions, results, costs and timing of, discovery, preclinical studies and clinical trials of our current and future product candidates, including AlloNK (AB-101), AB-201 and AB-205;

•the costs and timing of manufacturing for our product candidates, including continuing to develop our own manufacturing capabilities;

•the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities;

•the cost of obtaining, maintaining and protecting our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;

•the cost of establishing a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;

•the cost and timing of completion of commercial-scale manufacturing activities;

•the cost of making royalty, milestone or other payments under current and any future in-license agreements;

•the timing and amount of the milestone or other payments made to us under our current or any future collaboration agreements;

•costs associated with growing our workforce and retaining and motivating our employees;

•the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale;

•costs associated with any products or technologies that we may in-license or acquire;

•the costs associated with being a public company; and

•our implementation of additional internal systems and infrastructure, including operational, financial and management information systems.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of common stock. Debt financing and preferred 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 additional funds through collaborations, strategic

alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Discovery and Development of our Product Candidates

Our approach to the development of NK cell-based product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.

Our success depends on our ability to develop, obtain regulatory approval for and commercialize our product candidates utilizing our NK cell therapy platform, including manufacturing capabilities, which leverages relatively novel technologies. While we have had favorable preclinical and early clinical study results based on our platform, we are early in our development efforts and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Our understanding of NK cell biology is continuously evolving and this is particularly true in relation to autoimmune diseases where there is limited clinical data available. In particular, our approach in developing treatments for autoimmune diseases with NK cell-based therapies is novel and we have limited experience in doing so as our resources and processes have historically been focused on the development of NK cell-based therapies for cancer. We may also experience timeline delays or serious adverse events, and our product candidates may never become commercialized. All of our product candidates will require significant additional clinical and non-clinical development, review and approval by the FDA or comparable foreign regulatory authorities in one or more jurisdictions, substantial investment, and significant marketing efforts before they can be successfully commercialized. Our methodology and novel approach to cellular therapy may be unsuccessful in identifying additional product candidates, and any product candidates based on our platform may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. Further, because all of our product candidates and development programs are based on our NK cell therapy platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs. For example, if our clinical trials of AlloNK encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for our other product candidates in our pipeline could be significantly impaired.

The FDA has cautioned consumers about potential safety risks associated with T-cell therapies. The FDA has approved only a few cell-based therapies for commercialization and to our knowledge, no NK cell-based therapy has been approved for commercial use by any regulatory authority. Additionally, human primary cells are subject to donor-to-donor variability, which can make standardization more difficult. Understanding and addressing variability in the quality of a donor's cells, could ultimately affect our ability to produce product in a reliable and consistent manner and treat certain patients. As a result, the development and commercialization pathway for our product candidates may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

In addition, the biopharmaceutical industry is characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our NK cell-based approach. If we fail to stay at the forefront of technological change in utilizing our platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete, or limit the commercial value of our product candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our manufacturing process that we believe we derive from our platform. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our platform and potential of our product candidates.

There is currently no cell therapy approved in the United States or elsewhere in the world for the treatment of any autoimmune disease, and our research and development activities related to AlloNK for treatment of autoimmune diseases, such as SLE, LN, RA, PV, GPA / MPA, and other autoimmune diseases, may never lead to an approved product.

We are evaluating AlloNK in combination with B-cell targeted mAbs to treat autoimmune diseases, such as SLE, LN, RA, PV, GPA / MPA. There is currently no cell therapy approved in the United States or elsewhere in the world for the treatment of any autoimmune disease. We cannot be certain that our approach will lead to the development of an approvable or marketable product. We may not succeed in demonstrating safety and efficacy of AlloNK in combination with B-cell targeted mAbs for the treatment of autoimmune diseases in our ongoing or anticipated clinical trials or in larger-scale clinical trials. Advancing AlloNK in development creates significant challenges for us, including:

- obtaining marketing approval, as the FDA and other comparable foreign regulatory authorities have yet to approve a cell therapy for the treatment of any autoimmune disease;
- if AlloNK in combination with a B-cell targeted mAb is approved, educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our product into their clinical practice; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of developing product candidates and obtaining regulatory approval for any product candidates that we develop.

The clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates.

Regulatory requirements in the United States and in other countries governing cell therapy products are evolving and the FDA or comparable foreign regulatory authorities may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, within the FDA, the Center for Biologics Evaluation and Research (CBER) restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell therapy products, including NK cell-based products, such as ours. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in FDA or comparable foreign regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions.

We have concentrated our research and development efforts on utilizing NK cell-based therapies. To date, the FDA has approved only a few cell-based therapies for commercialization and no NK cell-based therapy has been approved for commercial use by any regulatory authority. The processes and requirements imposed by the FDA or comparable foreign regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our product candidates. Because our platform is novel, and cell-based therapies are relatively new, especially as potential treatments for autoimmune diseases, regulatory authorities may lack experience in evaluating product candidates like our product candidates. This novelty may lengthen the regulatory review process, including the time it takes for the FDA or comparable foreign regulatory authorities to review our INDs or comparable foreign applications if and when submitted, increase our development costs and delay or

prevent commercialization of our product candidates. Additionally, advancing novel immune-oncology therapies creates significant challenges for us, including:

- educating medical personnel regarding the potential side-effect profile of our product candidates and, as the clinical program progresses, on observed side effects with the product candidates;
- training medical personnel;
- enrolling sufficient numbers of patients in clinical trials; and
- continuing to develop a manufacturing process to support the clinical testing of our product candidates.

We must be able to overcome these challenges in order for us to develop, commercialize and manufacture our product candidates.

As we advance our product candidates, we will be required to consult with the FDA and comparable foreign regulatory authorities and our product candidates will likely be reviewed by an FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

In addition, either advances or adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy products, and cellular immunotherapies in particular, may cause the FDA and comparable foreign regulatory authorities to revise the requirements for approval of any product candidates we may develop, and may otherwise negatively affect our ability to develop and commercialize our product candidates. The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

We are early in our development efforts and are substantially dependent on the success of our lead product candidate, AlloNK, which is in early clinical development. Although we have other product candidates in our pipeline being developed by our partners, all of our other internally developed product candidates are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts and are substantially dependent on the success of our lead product candidate, AlloNK, which is in early clinical development. Although we have other product candidates in our pipeline being developed by our partners, all of our other internally developed product candidates are still in the preclinical or discovery stages. We have not yet completed any clinical trials for any product candidate. We will need to progress AlloNK through our recently initiated trial and progress our other early product candidates through preclinical studies and submit INDs to the FDA or comparable foreign regulatory applications to applicable foreign regulatory authorities prior to initiating clinical trials.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful enrollment in, and completion of, clinical trials with favorable results;
- completion of preclinical studies with favorable results;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;

•allowance to proceed with clinical trials under INDs by the FDA or under similar regulatory submissions by applicable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;

•demonstrating the safety and efficacy of our product candidates to the satisfaction of the FDA and other applicable foreign regulatory authorities;

•receipt of regulatory approvals from applicable regulatory authorities, including new drug applications (NDAs) from the FDA and approvals from comparable foreign regulatory authorities and maintaining such approvals;

•making arrangements with third-party manufacturers, or manufacturing sufficient quantities of product candidates for clinical and commercial use using our own facilities;

•establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;

•establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;

•acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;

•effectively competing with other therapies;

•obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;

•maintaining an acceptable safety profile of our products following approval; and

•building and maintaining an organization of people who can successfully develop our product candidates.

We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it will take several years before we can demonstrate the safety and efficacy of a product candidate sufficient to warrant approval for commercialization, if we can do so at all. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Current clinical data regarding the efficacy of NK cell therapies against autoimmune diseases are limited, raising uncertainties about the therapeutic benefits of treatments like AlloNK for conditions such as SLE, LN, RA, PV, GPA / MPA and other autoimmune diseases. Moreover, these therapies may not prove to be competitive compared to existing treatments for autoimmune diseases.

While we believe in the potential of our allogeneic NK cell-based product candidate, AlloNK, in combination with a B-cell targeted mAb may have a clinical benefit for autoimmune diseases, such as SLE, LN, RA, PV and GPA / MPA, the use of NK cell-based therapies in combination with mAbs represents a novel approach for the treatment of autoimmune disease, and is supported by limited clinical data. To date, the FDA has not approved any cell therapies for autoimmune diseases, adding to the uncertainty surrounding our ongoing clinical trials.

Our belief that AlloNK may be effective as a treatment for autoimmune disease is based on our interpretation of positive clinical data from academic groups and commercial entities using auto-CAR-T or CAR-NK in a limited autoimmune disease patient cohort, preliminary data from our collaborator Affimed in their ongoing investigation of AlloNK in a Phase 2 trial in combination with acimtamig, a CD30-targeted NK cell engager, in CD30+ Hodgkin lymphoma (HL), as well as our own preliminary data from our ongoing Phase 1/2 clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL, which demonstrated complete responses in B-NHL patients as measured by imaging of tumor lesions. We have made certain assumptions regarding the approach responsible for the preliminary activity shown in the reported studies and how that approach and our own preliminary data from our Phase 1/2 clinical trial in patients with aggressive B-NHL will translate to patients with autoimmune diseases, such as LN, which may not be correct.

We cannot be certain whether AlloNK in combination with a B-cell targeted mAb will effectively treat LN, other manifestations of SLE, RA, PV, GPA / MPA or any autoimmune disease for that matter, nor can we guarantee its competitiveness against auto-CAR-T. Additionally, we face competition from numerous cell therapy companies with strong oncology backgrounds, all pursuing development programs in autoimmune diseases, which could hinder our efforts to successfully develop and commercialize AlloNK in combination with a B-cell targeted mAb.

If our clinical trials reveal insufficient activity or unfavorable tolerability of AlloNK in combination with a B-cell targeted mAb against autoimmune diseases, such as SLE, LN, RA, PV and GPA / MPA, encounter delays in advancing AlloNK through clinical development, or if we struggle to compete with other companies in developing and marketing AlloNK in combination with a B-cell targeted mAb, it would significantly impact the commercial prospects of AlloNK, as well as our business, financial condition and growth outlook.

We are developing, and in the future may develop, other product candidates in combination with other therapies, which exposes us to additional risks.

We are developing AlloNK for combination with approved B-cell targeted mAbs. For example, our ongoing Phase 1/2 clinical trial is administering AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL. Beyond rituximab and other anti-CD20 mAbs, we have already conducted numerous preclinical studies in which we have shown cytotoxic activity of AlloNK in combination with other approved B-cell targeted mAb therapies, such as anti-CD19 and anti-CD38 mAbs. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate. There is also a risk that safety, efficacy, manufacturing or supply issues could arise with these other existing therapies. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in negative or inconclusive results that the product candidate or other therapy does not produce when used alone or in combination with a different therapy. This could result in our own products being removed from the market or being less successful commercially. Additionally, the results observed in combinations of any of our product candidates with another therapy may not be predictive of future results of combinations of our product candidates in other combinations or indications.

We may also evaluate our future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

Interim, topline and preliminary data from our preclinical studies or clinical trials that we announce or publish from time to time may not be predictive of future results and may change as more patient data become available and are subject to audit and verification procedures, which could result in material changes to the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our preclinical studies, clinical trials or planned clinical trials, which is based on a preliminary analysis of then-available data. The results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, such data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, topline, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient

enrollment continues and more patient data become available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects.

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

Moreover, results from previous preclinical studies or clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies of our product candidates or having successfully advanced through initial clinical trials.

Clinical trials are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

The clinical trials and manufacturing of our product candidates are 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 drug 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.

Clinical testing is expensive and takes many years to complete, and is subject to uncertainty. Our planned clinical trials may not be conducted as planned or completed on schedule, if at all. Delays and failures can occur at any time during the clinical trial process. Even if our future clinical trials are completed as planned, their results may not support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our future clinical trial results may not be successful.

In addition, even if our planned trials are successfully completed, the FDA or comparable foreign regulatory authorities may not 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 comparable 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.

To date, we have not completed any clinical trials required for the approval of our product candidates. We may experience delays in conducting any clinical trials, and we do not know whether our clinical trials will begin on time, will need to be redesigned, will recruit and enroll patients on time or have data readouts or be completed on schedule, or at all. Events that may prevent successful or timely commencement, readouts, and completion of clinical development and preclinical studies include:

•inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;

•delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials, or failure to do so;

•delays in reaching agreement with the FDA, or other comparable foreign regulatory authorities as to the design or implementation of our clinical trials, or failure to do so;

•delays in or failure to obtain regulatory approval to commence a clinical trial;

•delays in or failure to reach an agreement on acceptable terms with clinical trial sites or prospective contract research organizations (CROs) the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;

•delays in or failure to obtain institutional review board (IRB) approval or positive ethics committee opinion at each site;

•delays in or failure to recruit suitable patients to participate in a clinical trial;

•delays in or failure to develop and validate the companion diagnostic to be used in a clinical trial, if applicable;

•delays in or failure to have patients complete a clinical trial or return for post-treatment follow-up;

•clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;

•failure to perform in accordance with the FDA's GCP requirements, or applicable regulatory guidelines in other countries;

•the serious, life-threatening diseases of the patients enrolled in our clinical trials, who may die or suffer adverse medical events during the course of the trials for reasons that may not be related to our product candidates;

•failure in addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

•failure to add a sufficient number of clinical trial sites; or

•failure to manufacture sufficient quantities of product candidate for use in clinical trials.

•We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:

•we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;

•clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;

•the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

•our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

•we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, a finding that the participants are being exposed to unacceptable health risks;

•adverse events suffered by clinical trial participants that may ultimately be determined to be unrelated to our product candidates;

•the cost of clinical trials of our product candidates may be greater than we anticipate and we may elect not to cover the costs;

•the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

•regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and

•any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

•incur unplanned costs;

•be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;

•obtain marketing approval in some countries and not in others;

•obtain marketing approval for indications or patient populations that are not as broad as intended or desired;

•obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;

•be subject to additional post-marketing testing requirements; or

•have the product removed from the market after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards (IRBs) or ethics committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board (DSMB) for such trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination 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 comparable foreign 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 drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Our lead product candidate, AlloNK, will require extensive clinical testing before we are prepared to submit a BLA or MAA for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, or other comparable foreign regulatory authorities on our clinical development program, and the FDA or such other comparable foreign regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We also cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause serious adverse events or undesirable side effects or have other properties that may delay or prevent regulatory approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

We have not yet completed any human clinical trials of our product candidates. Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

While we believe the interim data reported to date from our Phase 1/2 B-NHL clinical trial indicate that NK cell-based therapies may have the potential to be better tolerated as compared to T cell based therapies due to biologic differences between these cell types there remains a risk of serious adverse events. In addition, historically, clinical trials using NK cell therapies in human subjects have been well-tolerated; however, it is possible that adverse events, including CRS, neurotoxicity or graft-versus-host disease will occur in human subjects during clinical trials.

Furthermore, clinical trial results could reveal an unacceptable severity or incidence of other adverse events, including heart and lung problems or life-threatening infections. Any such findings could cause delays in completion or cancellation of clinical programs. Furthermore, in some instances, the diseases we may be seeking to treat may be less serious than the later stage cancers traditionally being treated with cell therapies or other immunotherapy products. Therefore, we believe the FDA and comparable foreign regulatory authorities may apply a different risk-benefit threshold to our product candidates pursuing autoimmune indications such that any potential harmful side effects that may outweigh the benefits of such product candidates would require us to cease clinical trials or abandon or limit our development of these product candidates or would cause the FDA or comparable foreign regulatory authorities to deny marketing applications for these product candidates. We believe for the FDA and other regulatory authorities may weigh adverse events in the autoimmune patient populations being pursued with cell-based therapies, such as in our ongoing clinical trials, may be lower than it is in oncology, and the risks of negative impact from these toxicities may therefore be higher for our autoimmune programs than for our oncology programs or the oncology programs of others.

If unacceptable side effects or deaths arise in the development of our product candidates, we, the FDA, the IRBs or ethics committees at the institutions in which our studies are conducted, DSMB or comparable foreign regulatory authorities could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. For example, the FDA put our Phase 1/2 clinical trial of AlloNK in combination with rituximab in patients with relapsed or refractory B-NHL on clinical hold in April 2021 due to a patient death and lifted the clinical hold in June 2021 after our investigation and amendments to the clinical trial protocol. Although there was no definitive cause of death, the autopsy findings included widespread metastatic disease and cardiovascular disease, and concluded that the death was possibly due to cardiac arrhythmia. The principal investigator determined that this serious adverse event was not related to AlloNK. We may observe undesirable side effects and we may not be able to complete a clinical trial for AlloNK or any of our other product candidates without further delays or at all. Further undesirable side effects, dose-limiting toxicity events, or deaths in clinical trials with our product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical trials, to require additional studies, dose de-escalation, or additional protocol amendments, or otherwise to delay or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect site initiation, patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

We study our product candidates in patient populations with significant comorbidities, and these patients may also receive treatment with cytotoxic lymphodepletion agents, cytokines, monoclonal antibodies and/or other treatments that may result in deaths or serious adverse or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients treated with our product candidates in clinical trials may also receive treatment with cytotoxic lymphodepletion agents, cytokines, monoclonal antibodies and/or other treatments, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of seriously ill patients in our autoimmune clinical trials, and critically ill patients in our oncology clinical trials may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our existing product candidates or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process subject to various external factors beyond our control that may cause delays or complications.

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 not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trials' conclusion as required by the FDA or other comparable foreign regulatory authorities. We may experience difficulty in patient enrollment in our clinical trials for a number of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents for participation in our clinical trials; and
- the risk that patients enrolled in clinical trials will not remain in the trial through the completion of evaluation.

Competing with numerous ongoing trials and established therapies poses a challenge in recruiting patients. Our clinical trials may also compete with other clinical trials of product candidates that are in a similar cellular immunotherapy area as our product candidates, and this competition could 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. Additionally, for our ongoing or any future clinical trials of AlloNK for the treatment of other autoimmune diseases, the number of qualified clinical investigators is limited, so 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 site. Recent announcements of clinical trial plans by various cell therapy companies targeting autoimmune diseases, including indications we are pursuing, has resulted in competition for investigators and patients in our ongoing clinical trials, and may continue to intensify future competition in any other AlloNK clinical trials we may initiate in the future for the treatment of other autoimmune diseases. Failure to enroll a sufficient number of patients promptly could lead to delays or failure in completing our trials, hindering the development and commercialization of our product candidates within certain patient subgroups or altogether.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

In order to obtain FDA or comparable foreign regulatory authority approval to market a new biological product we must demonstrate proof of safety, purity and potency, or efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. AlloNK is our only product candidate to enter clinical development. Before we can commence clinical trials for additional product candidates, we must complete extensive preclinical testing and studies that support our planned INDs in the United States and comparable applications outside the United States.

We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or comparable foreign regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we may not submit INDs or similar applications for our preclinical programs within our anticipated timelines, if at all, and submission of INDs or similar applications may not result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design; and
- the FDA (or comparable foreign regulatory authorities) not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, because standards for pre-clinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre-IND proposal, the FDA may not accept the IND submissions as presented, in which the clinical trial timeline could be delayed.

We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our NK cell therapy platform. We are seeking to do so through our collaborations with GC Cell and Affimed, and may also explore additional strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different autoimmune diseases or cancers may require changes to our manufacturing processes, which may slow down development of or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may choose to cease development if we determine that clinical results do not show promise;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;

•a product candidate may 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; and

•a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, select certain other therapies to test in combination with our product candidates or treatment for a specific type of autoimmune disease or cancer, and we may forego or delay pursuit of opportunities with certain programs or product candidates or combinations or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

Results of any patient who receives our product candidate in an IIT should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for regulatory approval.

Before seeking regulatory approval for any of our product candidates, we must demonstrate statistically significant evidence of both safety and effectiveness in well-controlled clinical trials. However, we do not control the design, administration, or timing of IITs. We rely on investigators and physicians to ensure their compliance with clinical and regulatory requirements when using our product candidates for these trials. Failure to comply could expose us to liability.

While IITs may provide valuable insights, their results cannot be used to establish safety or efficacy for regulatory approval. In fact, they may identify concerns that could impact our findings or ongoing trials, potentially delaying or jeopardizing regulatory approval from the FDA or other regulatory bodies. If results from IITs differ from our sponsored trials or raise concerns, regulatory authorities may question our sponsored trial results and subject them to greater scrutiny. This could result in the need for additional clinical data, delaying clinical development and approval of our product candidates.

Moreover, the patient population in such trials is at high risk for serious adverse events. If these events are attributed to our product candidates, it could negatively impact their safety profile, leading to delays or failure in obtaining regulatory approval or successfully commercializing our drug candidates. Additionally, our supply capabilities may limit patient enrollment in these trials. We may need to restructure or pause supply to enroll sufficient patients in our sponsored trials, potentially leading to adverse publicity or other disruptions.

In summary, while IITs offer valuable insights, they also pose regulatory and operational challenges that could impact our ability to bring our product candidates to market.

The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

We select the targets for development of our product candidates based on a number of factors, including the estimated patient populations where we believe there is a meaningful addressable market opportunity. However, our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, alternative therapies and product pricing and reimbursement. For example, we intend to prioritize

evaluation and seeking approval for AlloNK in combination with a B-cell targeted mAb in autoimmune diseases. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates we use should be viewed with caution. Further, the data and statistical information we use, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Disruptions at the FDA and other government agencies or comparable foreign regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspectional operations, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs or other public health crisis were to occur that prevented the FDA or comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Manufacturing and Our Reliance on Third Parties

If third parties that we rely on to conduct clinical trials 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.

We do not independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. In addition, our partner GC Cell will be engaging in initial clinical development for AB-201, and has dosed initial patient for AB-205 outside our licensed territories to generate initial proof of concept data. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including GCP for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the competent authorities of the EU Member States, and comparable foreign regulatory authorities for any drugs in clinical development. The FDA and competent authorities of EU Member States enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection,

the FDA or comparable foreign regulatory authorities will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices (cGMP) regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, we will rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including clinical trial conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff.

Communicating with outside parties can also be challenging, potentially leading to mistakes, as well as difficulties in coordinating activities. Outside parties may:

•have staffing difficulties;

•fail to comply with contractual obligations;

•experience regulatory compliance issues;

•undergo changes in priorities or become financially distressed; or

•form relationships with other entities, some of which may be our competitors.

If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If 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 are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, refusal to accept or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates.

We may, from time to time, such as for our ongoing clinical trials, establish partnerships in relation to our clinical trials, receiving advisory services and other support from third parties. Although we believe that these partnerships will enable us to accelerate the development of our product candidates and clinical trials, we cannot guarantee that such collaborations will be successful and, in the event they are not, we may lose our competitive advantage and/or incur additional costs.

Our collaboration agreements with Affimed, GC Cell and any future collaborations with third parties to develop or commercialize our product candidates, mean that our prospects with respect to the product candidates involved will depend in significant part on the success of those collaborations.

Our collaborations, including our collaborations with Affimed and GC Cell, and any future collaborations we may enter with third parties, could result in the following risks:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could fail to conduct trials on the timeline we expect or otherwise fail to support our partnered trials;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators could encounter safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems with our partnered trials;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our 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 litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

In addition, if conflicts arise between our collaborators and us, our collaborators may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Our collaborators may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

As a result, if we enter into collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, such as our agreements with GC Cell and Affimed, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. Following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction.

We may seek to form collaborations in the future with respect to our product candidates, but may not be able to do so, which may cause us to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may seek to collaborate with pharmaceutical and biotechnology companies to develop and commercialize such product candidates, such as our collaborations with Affimed. 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.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future 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 them as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations.

The manufacture of cell therapy products is novel, complex and subject to multiple risks. We could experience manufacturing problems, and/or we could be required to or choose to modify our manufacturing processes, which could result in delays in the development or commercialization of our product candidates or otherwise harm our business.

Our product candidates utilize primary human NK cells, and the process of manufacturing such product candidates is complex, highly regulated and subject to numerous risks. As a result of these complexities, manufacturing our cellular therapy product candidates is generally more complicated than traditional small-molecule chemical compounds or biologics. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Moreover, the manufacturing processes for certain of our existing CAR-NK cell product candidates have not been tested at full scale.

Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We plan to make changes to our manufacturing processes for various reasons, such as to control costs, meet new or additional regulatory requirements, achieve scale, decrease processing time, increase manufacturing success rate, to facilitate the development of future product candidates or for other reasons, and we cannot be sure that even minor changes in these processes will not cause our current or future product candidates to perform differently and affect the results of our ongoing and planned clinical trials or the performance of the product once commercialized. Changes to our processes made during the course of clinical development will require us to amend our IND submission to the FDA to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. Other changes to our manufacturing processes made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. This could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, we may be required to make further changes to our processes and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

We may experience unforeseen events during, or as a result of, ramping up our manufacturing process that could result in delays in manufacturing sufficient quantities of our product candidates or otherwise harm our business.

We currently rely on GC Cell for the manufacturing of certain of our product candidates. While we have built our own clinical manufacturing facility and may decide to operate our manufacturing facility at commercial-scale, we may encounter delays, quality or other issues if and when we begin to use our manufacturing facility for supply, and will continue to rely on GC Cell at least partially for manufacturing of our product candidates in the near term.

We currently rely on GC Cell to manufacture certain of our product candidates. If GC Cell were to breach their agreement with us or otherwise fail to perform for any reason, including due to the loss of key members of GC Cell's management or other key employees, we likely would experience delays while we identify and qualify a replacement manufacturer and we may be unable to do so on terms that are favorable to us, which may make it more difficult for us to develop our product candidates and compete effectively. We have built our own clinical manufacturing facility and may decide to operate our own manufacturing facility at commercial-scale, or may elect to contract with other third-party contract manufacturers. Our cGMP manufacturing center is currently fully functional, but we may also encounter delays or quality or other issues as we begin to use our manufacturing facility or rely on other third-party contract manufacturers given the complexity of manufacturing cell therapies. We will continue to rely on GC Cell at least partially for manufacturing our product candidates in the near term. Any disruption in the supply of our product candidates could result in delays in our clinical trials, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

Our partial reliance on third parties for manufacturing increases the risk that supply of our product candidates may become limited or interrupted or may not be of satisfactory quality and quantity.

While we have built our own clinical manufacturing facility, we currently do not operate our manufacturing facilities at commercial-scale and outsource the manufacturing of our product candidates to third parties, including GC Cell, for certain of our product candidates. Moreover, while we are operating our own clinical manufacturing facility and may decide to operate our manufacturing facility at commercial-scale, we currently have limited personnel with experience in commercial drug manufacturing and currently lack the full resources and capabilities to manufacture any of our product candidates on a commercial scale. Our reliance on GC Cell and on a limited number of third-party manufacturers exposes us to the following risks:

We may continue to depend on certain third-party manufacturers and we may be unable to identify alternative manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or comparable foreign regulatory authorities may require us to submit additional information or have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our products.

- GC Cell or any future third-party manufacturer might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- GC Cell and any other contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- GC Cell and any future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, corresponding state agencies and comparable foreign regulatory authorities to monitor and ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. We have limited control over third-party manufacturers' compliance with these regulations and standards. Despite our efforts to audit and verify regulatory

compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations.

•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.

•GC Cell and any future third-party manufacturers could breach their agreement with us.

Though we have built our own clinical manufacturing facility, we expect that we will continue to rely on third parties for various manufacturing needs.

Manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our contract manufacturing organizations to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of our program materials for clinical study or enforcement action from the FDA or comparable foreign regulatory authorities. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulatory requirements could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, clinical holds, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates, if approved, and significantly harm our business, financial condition, results of operations and prospects. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis.

We are dependent on third parties to acquire, ship and store our cord blood units, NK cell master cell banks and drug product lots, viral vectors, and master and working feeder cell banks, and any disruption, quality concerns, damage or loss would cause delays in replacement and our business could suffer.

Our product candidates and certain other materials generated or used during their production, including cord blood units, viral vectors and working feeder cell banks, are acquired from and shipped by third parties and stored in freezers maintained by us and by third parties. In addition, our master cell banks are stored in freezers maintained by third parties. If there is a disruption to the supply of these materials, if available materials fail to meet quality standards, or if any of these materials are damaged while in transit or while stored at these facilities, including by the loss or malfunction of these freezers or back-up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement products, which could adversely impact our clinical supply and delay our clinical trials and preclinical studies. If we are unable to establish replacement materials in a timely fashion, we could incur significant additional expenses and potential liability to our clinical trial patients whose treatment is delayed, and our business could suffer.

Our cell therapy products depend on the availability of reagents and specialized materials and equipment, including cord blood and viral vectors, which in each case are required to be acceptable to the FDA and comparable foreign regulatory authorities, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We and our third-party manufacturers rely on third-party suppliers for various components, materials and equipment required for the manufacture of our product candidates, some of which are single-source products, and do not have supply arrangements for certain of these components.

Manufacturing of our product candidates, including by GC Cell and certain other of our third-party manufacturers, requires many reagents and other specialty materials and equipment, including cord blood and viral vectors, some of which are sourced from sole suppliers. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to possible adverse events. We and our third-party manufacturers rely on the general commercial availability of materials required for the manufacture of our product candidates, and 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. Even if we or our third-party manufacturers are able to enter into such contracts, we may be limited to a sole

third-party for the supply of certain required components. An inability by us or our third-party manufacturers 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, availability of raw materials, 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.

If we or our third-party manufacturers are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect our clinical development of our product candidates and harm our business.

If our third-party suppliers use hazardous, non-hazardous, biological or other 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. We and our suppliers are subject to federal, state and local laws and regulations in the United States and by foreign governmental authorities governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, neither we nor our suppliers can 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.

Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of cell therapy manufacturing, there is a risk of contamination. If microbial, viral or other contaminants are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, delay our clinical trials, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. These raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Our Product Candidates

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

The biopharmaceutical industry in general, and the cell therapy field in particular, is characterized by rapidly advancing and changing technologies, intense competition and a strong emphasis on intellectual property. We face

substantial and increasing competition from large and specialty biopharmaceutical companies, as well as public and private medical research institutions and governmental agencies. A large number of cell therapy companies with capabilities and expertise in oncology are advancing development programs in autoimmune diseases. Our known biopharmaceutical competitors that are developing allogeneic CAR-NK or CAR-T cell therapies or T-cell engaging bispecific antibodies include, but may not be limited to, the following: Adicet Bio, Inc., Allogene Therapeutics, Inc., Amgen Inc., Autolus Therapeutics plc, Bristol-Myers Squibb Co, Cabaletta Bio, Inc., Candid Therapeutics, Inc., Caribou Biosciences, Inc., Cartesian Therapeutics, Inc., Century Therapeutics, Inc., Cullinan Therapeutics Inc., Fate Therapeutics, Inc., Galapagos NV, Gilead Sciences, Inc., Gracell Biopharmaceuticals, Inc. (acquired by AstraZeneca), GSK plc, iCell Gene Therapeutics Inc., ImmPACT Bio USA, Inc. (acquired by Lyell Immunopharma, Inc.), ITabMed Co., Ltd., Johnson & Johnson, Kyverna Therapeutics, Inc., Luminary Therapeutics, Inc., Merck & Co., Inc., Nkarta, Inc., Novartis AG, Regeneron Pharmaceuticals, Inc., Roche, Sana Biotechnology, Inc., Sanofi, Shoreline Biosciences Inc., Synthekine Inc., Takeda Pharmaceuticals Company Limited, Wugen, Inc. and Xencor, Inc.

Our competitors will also include companies that are or will be developing other targeted therapies, including small molecule or antibodies for the same indications that we are targeting. It is also possible that new competitors, including those developing similar products or alternatives to cellular immunotherapy product candidates, may emerge and acquire significant market share. Many of our current or potential competitors have significantly greater financial, technical and human resources, as well as more expertise in research and development, manufacturing, preclinical testing, conducting clinical studies and trials and commercializing and marketing approved products. Mergers and acquisitions in the biopharmaceutical industry may result in even greater resource concentration among a smaller number of competitors.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate 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. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of autoimmune disease and cancer, we cannot accurately estimate the potential revenue from our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may also be particularly difficult because of the higher prices often associated with such drugs. 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. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, 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.

Obtaining coverage and reimbursement 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 the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. 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. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the CMS revises the reimbursement systems used to reimburse healthcare providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Additionally, any companion diagnostic test that we develop will be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

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. Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some foreign countries, particularly those in Europe, 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. The EU provides options for EU 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, it may refuse to reimburse a product at the price set by the manufacturer 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. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. The downward pressure on healthcare costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

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

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our product candidates, if approved for commercial sale; and
- loss of revenue.

Risks Related to Government Regulation

The regulatory approval process of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval for any of our product candidates, and any such regulatory approval may be for a narrower indication than we seek.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and comparable foreign regulatory authorities in and outside the United States. We are not permitted to market any biological drug product in the United States or outside the United States until we receive approval of a BLA from the FDA or similar approvals from comparable foreign regulatory authorities. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA and similar applications must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA and similar applications must also include significant information regarding the chemistry, manufacturing and controls for the product, including with respect to chain of identity and chain of custody of the product.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

•disagreement with the design or conduct of our clinical trials;

•failure to demonstrate to the satisfaction of regulatory authorities that our product candidates are safe and effective, or have a positive benefit/risk profile for its proposed indication;

•failure of clinical trials to meet the level of statistical significance required for approval;

•disagreement with our interpretation of data from preclinical studies or clinical trials;

•the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;

•failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or

•changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, 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 product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. 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, as the FDA often adheres to the Advisory Committee's recommendations. Similar requirements may apply outside the United States.

Similar requirements apply in the EU. The EMA has a Committee for Advanced Therapies (CAT), that is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs). ATMPs include gene therapy medicinal products, somatic-cell therapy medicinal products and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for ATMP candidates that is submitted to the EMA for subsequent review by the Committee for Medicinal Products for Human Use (CHMP). In the EU, the development and evaluation of an ATMP must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape.

In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In addition, the EU pharmaceutical legislation is currently the subject of proposals for a complete review, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. On April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a number of changes to the regulatory framework governing medicinal products, including a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, the date of which cannot currently be anticipated. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a risk evaluation and mitigation strategy (REMS) or comparable foreign strategies. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially adversely affect our business, financial condition, results of operations and prospects.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

Because we are developing novel NK cell therapy product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear and may change. Regulatory requirements in the United States and in other countries governing cell therapy products have changed frequently and the FDA or

comparable foreign regulatory authorities may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, within the FDA, the CBER restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell therapy products, including NK and CAR-NK cell products such as ours. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates.

In addition to FDA oversight and oversight by IRBs under guidelines promulgated by the National Institutes of Health (NIH) gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (IBC) a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical study can begin at any institution, that institution's IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of cell therapy product candidates conducted by others may cause the FDA or comparable foreign regulatory authorities to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. In addition, adverse developments in clinical trials of cell therapy products conducted by others may cause the FDA or comparable foreign regulatory authorities to change the requirements for approval of any of our product candidates.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory authorities.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to operate our business as planned and to generate sufficient product revenue to maintain our business.

The FDA, the EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, the EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate mean. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, the EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its

applicable jurisdiction. If the FDA, the EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, 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. In order to obtain orphan drug designation, the request must be made 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. In the EU 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. The application for orphan designation must be submitted before the application for marketing authorization.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product 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 drug (including 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 product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees, fee waivers, protocol assistance and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirement for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. However, during such period, marketing authorizations may be granted to a similar medicinal product with the same orphan indication if: (i) the applicant can establish that the second medicinal product, although similar to the orphan medicinal product already authorized is safer, more effective or otherwise clinically superior to the orphan medicinal product already authorized; (ii) the marketing authorization holder for the orphan medicinal product grants its consent; or (iii) if the marketing authorization holder of the orphan medicinal product is unable to supply sufficient quantities of product. The EU exclusivity period can be reduced to six years, if, at the end of the fifth year a medicinal product no longer meets the criteria for orphan designation (i.e., the prevalence of the condition has increased above the orphan designation threshold or it is judged that the product is sufficiently profitable so as not to justify maintenance of market exclusivity).

We have received orphan drug designation for AB-201 in the United States, for the treatment of gastric and gastroesophageal junction cancer. Additionally, we may 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. Even if we obtain orphan drug designation, 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 we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. Similar considerations may apply outside the United States. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations In addition, orphan drug exclusivity does not prevent the FDA or European Commission from approving competing drugs for the same or similar indication containing a different active ingredient. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving these designations, and even if received, they may not benefit the development and regulatory approval process.

We may seek various designations by regulatory authorities, such as Regenerative Medicine Advanced Therapy Designation (RMAT) Breakthrough Therapy Designation, Fast Track Designation, or PRIority MEdicine (PRIME) Designation from regulatory authorities, for any product candidate that we develop. A product candidate may receive RMAT designation from the FDA if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and potential eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites post-approval, if appropriate. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

A Breakthrough Therapy is defined by the FDA as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the study can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

If a drug is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for Fast Track Designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. If granted, fast track designation makes a drug eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Products with Fast Track designation may also be eligible for accelerated approval and priority review, if the relevant criteria are met.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed

at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product 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. 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 potentially accelerated MAA assessment once a dossier has been submitted.

Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. The FDA and the EMA, as applicable, have broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for one or more of these designations, the applicable regulatory authority may determine not to grant it. We received Fast Track designation for AlloNK in combination with either rituximab or obinutuzumab to improve disease activity in patients with class III or class IV LN in February 2024. We also received Fast Track designation for AlloNK for IV infusion in combination with rituximab for the treatment of relapsed or refractory B-NHL origin to improve cancer response rates in January 2023. Fast Track designation does not guarantee an accelerated review of AlloNK or increase the likelihood that AlloNK will receive regulatory approval by the FDA. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures, as applicable. The FDA or EU, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign 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, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies 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.

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

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional

elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, the availability of our product candidates to be administered in rheumatology community centers, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements.

These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional 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. In addition, the FDA or comparable foreign regulatory authorities could require us to conduct another study to obtain additional safety or biomarker information.

Further, we will be required to comply with FDA and comparable foreign regulatory authorities' promotion and advertising rules, 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 and social media. Although the FDA and comparable foreign regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS or similar foreign program. Other potential consequences include, among other things:

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

FDA and comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the any administration may impact our business and industry. 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.

Additionally, the policies of the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. For example, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency

rulemaking process, any of which could adversely impact our business and operations. 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 be subject to enforcement action and our business, results of operations, and financial condition could be adversely affected.

Our relationships with customers, physicians, other healthcare professionals and third-party payors are subject, directly or indirectly, to federal, state, local and foreign healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.

Healthcare professionals and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors, customers and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations 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, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that may be alleged to be intended to induce prescribing, purchases or recommendations, including any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws, including the federal civil False Claims Act (FCA) and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Private individuals, commonly known as "whistleblowers," can bring federal civil FCA qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the 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;

•HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, which impose requirements on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, and their respective business associates that perform services for them that involve creating, receiving maintaining or transmitting protected health information (PHI) and their subcontractors that use, disclose, access, or otherwise process PHI, relating to the privacy, security and transmission of individually identifiable health information. Penalties for HIPAA violations can be significant. They vary greatly depending on the nature of violation, and could include civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI; the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

•federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we may be subject to state, local and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, in the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the EU. Relationships with healthcare professionals and associations are subject to stringent anti-gift statutes and anti-bribery laws, the scope of which differs across the EU. In addition, national "Sunshine Acts" may require pharmaceutical companies to report/publish transfers of value provided to healthcare professionals and associations on a regular (e.g., annual) basis.

Also, we may be subject to the following: state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental, third-party payors, including private insurers, or that apply regardless of payor; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures; state and foreign laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including certain arrangements we have with physicians who are paid in the form of stock or stock options for services provided to us, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties. 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, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We expect the product candidates we develop will be regulated as biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Patient Protection Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference 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 processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA, if any, should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the 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.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

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

The use of allogeneic NK cells as a potential autoimmune disease or cancer treatment may not become broadly accepted by physicians, patients, hospitals, rheumatology clinics, cancer treatment centers and others in the medical community. Factors that will influence whether our product candidates are accepted in the market include:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, rheumatology clinics, 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 incidence and severity of any side effects;

•product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities;

•limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;

•the availability of our product candidates to be administered in rheumatology community centers;

•the timing of market introduction of our product candidates as well as competitive products;

•the cost of treatment in relation to alternative treatments;

•our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;

•the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;

•relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and

•the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, rheumatology clinics, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidates, if approved.

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 healthcare system that could impact our ability to profitably sell our product candidates, if approved. In particular, in 2010 the Affordable Care Act was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid drug rebate program are calculated, 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. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new Patient-Centered Outcomes Research Institute.

Since its enactment, there have been executive, judicial and political challenges and amendments to certain aspects of the Affordable Care Act. It is unclear how other healthcare reform measures of the second Trump administration, if any, will impact our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions to Medicare payments to providers, which went into effect beginning on April 1, 2013 and due to subsequent legislative amendments to the statute will stay in effect through 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, which was previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning on January 1, 2024. 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on

anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. For example, the Inflation Reduction Act of 2022 (IRA), among other things, (i) directs the U.S. Department of Health and Human Services (HHS) to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law (the "Medicare Drug Price Negotiation Program"), and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In the EU, similar developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or Member State level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicinal products, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU Member States have resulted in restrictions on the pricing and reimbursement of medicinal products by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

We cannot predict the initiatives that may be adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections. 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 reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and information security. Our (or of the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, a disruption of our business operations, reputational harm and other adverse impacts to our business and financial condition.

We collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) sensitive and confidential information, including certain personal information, which subjects us to various obligations related to data privacy and information security, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively, HIPAA, federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal, state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws govern the processing of health-related and other personal information impose specific requirements relating to the privacy, security, and transmission of health-related and other personal information . We are subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act (MHMD) broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

In addition, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the CCPA applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside of the United States an increasing number of laws, regulations, and industry standards govern data privacy and security, Foreign data protection laws, including the EU General Data Protection Regulation (EU GDPR) and the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (UK GDPR) (collectively, the GDPR), may also apply to health-related and other personal data obtained outside of the United States and impose strict requirements for processing such data. For example, the GDPR imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA) and UK or in the context of our activities within the EEA and UK and provides for potential fines of up to the greater of €20 million under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue of a noncompliant undertaking, temporary or definitive bans on processing data, or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework (DPF) and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. For example, in May 2023, the Irish Data Protection Commission determined that a major social media company's use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1.2 billion Euro fine against the company and prohibited the company from transferring personal data to the United States. Regulators in the United States such as the Department of Justice are also increasingly scrutinizing certain personal data transfers and have proposed and may enact certain data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional data privacy and security laws and regulations that may affect how we conduct business.

In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials, white papers, and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process data on our behalf. In addition, these obligations may require us to change our business model.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; imprisonment of company officials; and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or the third parties upon which we rely obtain information may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our

product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

We are subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

We are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies" yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export our products, services and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

Risks Related to Our Intellectual Property

We depend substantially on intellectual property rights granted under our agreements with GC Cell. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our product candidates.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We depend substantially on our agreements with GC Cell, including the licenses granted thereunder. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. For example, our proprietary manufacturing methods depend on technology licensed to us by GC Cell. In addition, GC Cell in-licenses some of the intellectual property rights that GC Cell has licensed to us, or that we have the ability to access under our agreements with GC Cell. To the extent these licensors fail to meet their obligations under their license agreements with GC Cell, which we are not in control of, we may lose the benefits of our license agreements with these licensors. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

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

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. In addition, some of our patent rights are co-owned with GC Cell and others, and may in the future be co-owned with other third parties. We may need the cooperation of GC Cell and any future co-owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. It is also possible that our licensors' or co-owners' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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. We may not 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. Furthermore, we may be unable to in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties, which we identify as necessary for our product candidates.

If we are unable to obtain and maintain patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our proprietary manufacturing methods, proprietary technologies, product candidate development programs and product candidates. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to our current product candidates and any future product candidates we may develop. We seek to protect our proprietary position by filing or collaborating with our licensors and co-owners to file patent applications in the United States and abroad related to our proprietary technologies, development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in 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. Method of manufacturing patents protect only the manufacturing process. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product, but manufactured by a method that is outside the scope of the patented manufacturing method. Moreover, even if a competitor's manufacturing process does infringe or contribute to the infringement of method of manufacturing patents, such infringement is difficult to detect and therefore difficult to prevent or prosecute.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our proprietary products and technology, including

current product candidates, any future product candidates we may develop, and our NK cell therapy technology in the United States or in other foreign countries, in whole or in part. Alternately, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. It is possible that not all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. For example, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Even if patents do successfully issue and even if such patents cover our current product candidates, any future product candidates we may develop and our NK cell therapy technology, third parties may challenge their validity, ownership, enforceability or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable or circumvented. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any of our product candidates or gene regulation technology. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and our NK cell therapy platform under patent protection could be reduced. If any of our patents expire or are challenged, invalidated, circumvented or otherwise limited by third parties prior to the commercialization of our product candidate, and if we do not own or have exclusive rights to other enforceable patents protecting our product candidate or technologies, competitors and other third parties could market products and use processes that are substantially similar, or superior, to ours and our business would suffer.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our current or future product candidates or technology, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our ability to commercialize future product candidates. Any such outcome could harm our business.

We are a party to intellectual property license agreements with GC Cell which are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, royalties and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, or, in some cases, under other circumstances, the licensor may have the right to terminate the license, in which event we would not be able to market product candidate(s) covered by the license.

The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal, scientific and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Since patent applications in the United States and other jurisdictions are confidential for a period of time after filing, we cannot be certain that we were the first to file for patents covering our inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect our technology or products, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. We may become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our owned or licensed patent rights. For example, with respect to our licensed patents and jointly owned patents and patent applications from GC Cell, competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to the inventors of our licensed patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from biosimilar versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our product candidates, prohibit our use of proprietary technology or sale of products or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell, if approved, our product candidates. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. We may be subject to third-party claims including patent infringement, interference or derivation proceedings, post-grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our

ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. There may be third-party patents or patent applications with claims to compositions, formulations, or methods of treatment, prevention use, or manufacture of our product candidates or technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our ability to progress the clinical development of or commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license.

We also may be subject to third party claims arising from prior employment agreements and/or consulting agreements entered into by our officers, employees, independent contractors and/or consultants. Claims may include breach of nondisclosure, nonuse, noncompetition and non-solicitation provisions, intellectual property assignment and ownership, and misuse or misappropriation of intellectual property, trade secrets and other confidential information, among others. If a court of competent jurisdiction finds that we breached the provisions of third party consulting agreements, we may be prohibited from using certain intellectual property, trade secrets and confidential information, effectively blocking our ability to seek patent protection for our inventions and halting the progress of our clinical development and commercialization efforts.

In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's intellectual property rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated, as parties making claims against us may obtain injunctive or other equitable relief. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our products, services and technology. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Competitors may infringe our patents or other intellectual property. If we or one of our licensors or co-owners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness lack of written description, or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. The outcome of proceedings involving assertions of invalidity and

unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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

It is possible that our or our licensors' or co-owners' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are not complete or thorough. It is also possible that we have not identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000, and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, the EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could be filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates, if approved. If we fail to identify or correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We currently depend, and will continue to depend, on our license agreements, including our agreements with GC Cell. Further development and commercialization of our current or any future product candidates may require us to enter into additional license or collaboration agreements, including, potentially, additional agreements with GC Cell or any of our other licensors. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If any of our licenses or material relationships or any in-licenses upon which our licenses are based are terminated or breached, we may:

•lose our rights to develop and market our products;

•lose patent protection for our products;

•lose rights to important confidential know-how for manufacturing our products;

•experience significant delays in the development or commercialization of our products;

•incur significant extra costs in order to develop, manufacture and commercialize our products;

•not be able to obtain any other licenses on acceptable terms, if at all; or

•incur liability for damages.

These risks apply to any agreements that we may enter into in the future for our products or for any future product candidates. If we experience any of the foregoing, it could have a material adverse effect on our business, financial condition, results or operations and prospects.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property, particularly our patents. Obtaining and enforcing patents in the biotechnology and genetic medicine industries involve both technological and legal complexity. Therefore, obtaining and enforcing biotechnology and genetic medicine patents is costly, time-consuming and inherently uncertain. In addition, the Leahy-Smith America Invents Act (AIA) which was passed in September 2011, resulted in significant changes to the U.S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or co-owners' patent applications and the enforcement or defense of our or our licensors' or co-owners' issued patents. We may become involved in opposition, interference, derivation, inter partes review or other proceedings challenging our or our licensors' or co-owners' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. 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 Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Further, on June 1, 2023, the European Patent Package (EU Patent Package) regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC), for litigation involving European patents. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies provided by the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. We will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits, if any, of the new unified court.

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

The USPTO, European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, European and other patent agencies over the lifetime of the patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors or co-owners fail to maintain the patents and patent applications covering our product candidates or if we or our licensors or co-owners otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully progress clinical development of or commercialize our product candidates in any indication for which they may be approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' and co-owners' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors and co-owners have patent protection, but where enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our or our licensors' or co-owners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or co-owners' patents, requiring us or our licensors or co-owners to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the EU and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' or co-owners' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' or co-owners' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors or co-owners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions including EU countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors or co-owners are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors or co-owners are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors or co-owners obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- we or our licensors, co-owners, or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors, co-owners, or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;

•we or our licensors or co-owners may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;

•it is possible that our pending patent applications will not result in issued patents;

•it is possible that there are prior public disclosures that could invalidate our or our licensors' or co-owners' patents;

•issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

•we may not exclusively license our patents and, therefore, may not have a competitive advantage if such patents are licensed to others, including for example, under our license agreements with GC Cell, pursuant to which GC Cell and its upstream licensors retain the exclusive right over certain technologies;

•our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

•ownership, validity or enforceability of our or our licensors' or co-owners' patents or patent applications may be challenged by third parties; and

•the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider trade secrets and confidential know-how to be important to our business. We may rely on trade secrets and confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and confidential know-how are difficult to protect, and we have limited control over the protection of trade secrets and confidential know-how used by our licensors, co-owners, collaborators and suppliers. Because we rely on third parties to manufacture our product candidates, may continue to do so in the future and expect to collaborate with third parties on the development of our current product candidates and any future product candidates we develop, we may, at times, share trade secrets and confidential know-how with them. We also conduct joint research and development programs that may require us to share trade secrets and confidential know-how under the terms of our research and development partnerships or similar agreements. Under such circumstances, trade secrets and confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential know-how increases the risk that such trade secrets and confidential know-how become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our confidential know-how and trade secrets, a competitor's discovery of our trade secrets and/or confidential know-how or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Courts outside the United States are sometimes less willing to protect proprietary information,

technology and know-how. Further, we may need to share our trade secrets and confidential know-how with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets or confidential know-how, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets and confidential know-how, our competitors may discover them, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets and/or confidential know-how would impair our competitive position and have an adverse impact on our business.

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We may need to license additional intellectual property from third parties, and any such licenses may not be available or may not be available on commercially reasonable terms.

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 product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compositions and pre-existing pharmaceutical compositions. These pharmaceutical products may be covered by intellectual property rights held by others. We may be required by the FDA, or other comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. 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.

We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors.

While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self-executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such

claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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 rely on trade secret protection and confidentiality agreements to protect trade secrets, confidential know-how, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve proprietary information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and require all of our employees and key consultants who have access to our confidential know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. 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, 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.

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

We do and will continue to employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, consultants, collaborators, independent contractors and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the know-how or confidential information of their former employer or other third parties, we may be subject to claims that we or our employees, consultants, collaborators or independent contractors have inadvertently or otherwise used or disclosed know-how or confidential information of their former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents.

Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and if we do fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, which could result in customers seeking other sources for the technology, or in ceasing from doing business with us. Any such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to progress our clinical development programs or commercialize our technology or product candidate. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

Risks Related to Our Industry and Business

We will need to expand our organization, and we may experience challenges in managing this growth as we build our capabilities, which could disrupt our operations.

As of December 31, 2024, we had 89 full-time employees. We will need to expand our organization, and we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our future success depends on our ability to retain our key personnel 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 our executive officers, as well as the other members of our management, scientific and clinical 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 and, for certain of our executive officers, entitle them to receive severance payments in connection with their voluntary resignation of employment for good reason, as defined in the employment agreements.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees 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 highly specialized skills and experience required to develop, gain regulatory approval of and commercialize our product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous biopharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to advance the clinical development of and commercialize product candidates will be limited.

If our information technology systems or those of the third parties with whom we work or our data are or were compromised, we could experience adverse impacts resulting from such compromise or failure, including, but not limited to, interruptions to our operations such as our clinical trials, regulatory investigations or actions; litigation; fines and penalties; claims that we breached our data protection obligations; harm to our reputation; a loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and third parties with whom we work process confidential and sensitive data, including intellectual property, pre-clinical and clinical trial data, proprietary business information and personal information of employees, business partners and service providers (collectively, Confidential Information) necessary to conduct our business in our and the third parties' upon which we rely data centers and networks. The secure processing, maintenance and transmission of this Confidential Information is critical to our operations. Despite our security measures, our information technology and infrastructure, and those of third parties upon which we rely, including our current and future CROs, may be subject to attacks, damage and interruption

from hackers or internal bad actors, human error, misconfigurations, "bugs" and other technical vulnerabilities, fraud, malfeasance, computer viruses and malware (e.g., ransomware), cyber attacks, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), denial or degradation of service attacks, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence, natural disasters, terrorism, war and telecommunication and electrical failures or other disruptions. Such threats are prevalent, continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel, sophisticated nation states and nation-state supported actors, including via advanced persistent threat intrusions.

Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including Confidential Information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

Additionally, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities and utilizing network connections, information technology and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process Confidential Information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, clinical trials and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If these parties experience a security breach or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our systems and networks or the systems and networks of third parties that support us and our services.

Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. We take steps to detect, mitigate and remediate vulnerabilities in our information technology systems (such as our hardware and/or software and those of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security breach. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection and to remove or obfuscate forensic evidence.

We and certain of the third parties upon which we rely are from time to time subject to cyber attacks and security incidents. Although, to our knowledge, we have not experienced any material security breach to date, any such breach could compromise our networks and the Confidential Information stored there could be accessed, publicly disclosed, lost or stolen. While we have taken steps to protect the security of the Confidential Information

that we handle, there can be no assurance that our and the third parties' upon which we rely cybersecurity risk management program and processes, including policies, controls or procedures and other security measures that we have implemented will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information against current or future security threats. Our security measures could fail and result in unauthorized, accidental or unlawful access to, or disclosure, modification, misuse, loss or destruction of, our Confidential Information, including personal information. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security breaches. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and Confidential Information.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, regulators and investors, of security breaches, or to take other actions such as providing credit monitoring and identity theft protection services. The costs associated with the investigation, remediation and making such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such unauthorized access, disclosure or other loss of Confidential Information experienced by (or perceived to be experienced by) us or a third party with whom we work could also result in adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; financial loss; disruptions to our operations and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation; and other similar harms. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our Confidential Information could require substantial expenditures to remedy. 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 Information, we could incur liability and the further development of our product candidates could be delayed. Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Our business is subject to risks arising from pandemic and epidemic diseases.

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. Any future pandemic or epidemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of our product candidates for use in our clinical trials and research and preclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, alter the results of the clinical trial due to disease progression in participants, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future pandemic or epidemic disease outbreak could also potentially further affect the business of the FDA or other comparable foreign regulatory authorities, which could result in delays in meetings related to our ongoing or planned clinical trials, as well have an adverse impact on global economic conditions, which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

Our business could be affected by litigation, government investigations, and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry, and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental,

whistleblower, false claims, data privacy and security, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation, or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (1) the laws and regulations of the FDA, EU and comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (2) manufacturing standards; (3) data privacy and security laws, and fraud and abuse and other healthcare laws and regulations; or (4) other laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

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

We have incurred losses during our history, we expect to continue to incur significant losses for the foreseeable future, and we may never achieve profitability. Under current law, U.S. federal net operating losses (NOLs) incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in a taxable year is limited to 80% of taxable income in such year.

As of December 31, 2024, we had federal net operating loss carryforwards of approximately $99.7 million and state net operating loss carryforwards of $143.4 million. All of our federal net operating loss carryforwards as of December 31, 2024 can be carried forward indefinitely. State net operating loss carryforwards begin to expire in 2039. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards, research and development (R&D) credits and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. We have not completed a Section 382 ownership change analysis. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. Changes to U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes could further affect our ability to use our tax attributes in the future. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation informally titled the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to new and existing legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings and the deductibility of expenses or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges and could increase our future U.S. tax expense.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance factors. Some investors may use these factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies relating to corporate responsibility are inadequate, including if they believe our policies relating to our Pledge 1% Movement commitment are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance. The criteria by which companies' corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate certain initiatives and goals regarding environmental, social and governance matters, including with respect to the Pledge 1% Movement campaign, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors, employees and other stakeholders or our initiatives are not executed as planned, our reputation and financial results could be materially and adversely affected.

Risks Related to the Ownership of Our Common Stock

The trading price of our common stock is likely to be volatile and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of common stock at or above the price you paid. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many other factors, including:

- timing and results of our preclinical studies and clinical trials or those of our competitors;
- the costs and timing of manufacturing for our product candidates, including developing our own manufacturing capabilities;
- the success of existing or new competitive therapies, products or technologies;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- failure or discontinuation of any of our research or development programs;
- any termination or loss of rights under our GC Cell Research Services Agreement and our Master Agreement for Manufacturing Services with GC Cell;
- changes in the level of expenses related to any of our research or development programs;
- developments related to any existing or future collaborations;
- the recruitment or departure of key personnel;
- regulatory or legal developments in the United States and other countries;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in the structure of healthcare payment systems;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- changes in failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- changes in accounting principles; and
- the other factors described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K.

In addition, the stock market in general and the market for biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to operating

performance of the particular companies affected. Following price volatility, holders of securities may institute securities class action litigation against the issuer. If any of holders of our common stock were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our board of directors and senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities. Further, a decline in the financial markets and related factors beyond our control may cause the price of our common stock to decline rapidly and unexpectedly. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly control or influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Future sales and issuances of our securities, including pursuant to our equity incentive plans and our commitment to the Pledge 1% Movement, may cause dilution to our stockholders or decrease our stock price.

We expect that significant additional capital may be necessary to continue our planned operations, including for expanding product development, conducting clinical trials and commercializing our product candidates. We may seek additional capital through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of our product candidates. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

Pursuant to our 2024 Equity Incentive Plan (2024 Plan), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2024 Plan will automatically increase on January 1 of each calendar year, beginning on January 1, 2025 and continuing through and including January 1, 2034, by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2025 (through January 1, 2034), by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) 424,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Pursuant to our commitment to the Pledge 1% Movement campaign, in July 2021, our board of directors approved the reservation of up to 84,556 shares of our common stock (the Reserve) (which represented approximately 1.0% of our fully-diluted capitalization as of such date) that we may issue to or for the benefit of a charitable foundation established by us or other appropriate charitable recipients. The Reserve will be donated in equal installments over five years following our IPO or in full upon a sale of our company, in each case, first subject to certain per-share valuation thresholds for our common stock. We have not yet issued any of the Reserve. If any of the Reserve is issued pursuant to our Pledge 1% Movement commitment, such issuance may also dilute your ownership interest.

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

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.24 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies.

We have taken advantage of the reduced reporting burdens and the information we provide to stockholders will be different than the information that is available with respect to other public companies that are not emerging growth companies. It is possible that this may cause investors to find our common stock less attractive. 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 share price may be reduced or more volatile.

Even following the termination of our status as an emerging growth company, we may be able to take advantage of the reduced disclosure requirements applicable to "smaller reporting companies," as that term is defined in Rule 12b-2 of the Exchange Act, and, in particular, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. To the extent that we are no longer eligible to use exemptions from various reporting requirements, we may be unable to realize our anticipated cost savings from these exemptions, which could have a material adverse impact on our operating results.

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

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported.

Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in

increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations-Recent Accounting Pronouncements." As an emerging growth company, the JOBS Act allows us to delay adoption of new or revised accounting standards applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. However, we may elect to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. We may take advantage of these exemptions up until the time that we are no longer an emerging growth company.

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

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

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

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which are in effect, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;

•do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; and

•provide that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and any appellate court therefrom is the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action that is based upon a violation of a duty owed by any current or former director, officer, other employee or stockholder, to us or our stockholders; (iii) any claim or cause of action against us or any current or former director, officer or other employee, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any current or former director, officer or other employee, governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by applicable law and subject to the court having personal jurisdiction over the indispensable parties named as defendant; provided, however, that if the designation of such court as the sole and exclusive forum for a claim or action referred to in foregoing clauses (i) through (vi) would violate applicable law, then the United States District Court for the District of Delaware shall be the sole and exclusive forum for such claim or cause of action. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America

shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits and result in increased costs for investors to bring a claim. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

General Risk Factors

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly, particularly after we no longer qualify as an emerging growth company. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404) we are required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC. However, while we remain an emerging growth company or smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. In addition, if we identify one or more material weaknesses as a result of this implementation and evaluation process, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Unstable market and economic conditions, including any adverse macroeconomic conditions or geopolitical events, may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts,

rising interest rates, supply chain constraints, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of government tariffs, public health crises, military conflict, including the conflict between Russia and Ukraine and the ongoing conflicts in the Middle East, terrorism or other geopolitical events. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Sanctions imposed by the United States and other countries in response to military conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Section 404(a) of the Sarbanes-Oxley Act requires that beginning with our second annual report following our IPO, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an emerging growth company or smaller reporting company.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Additionally, the increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our common stock, our share price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our shares could be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our share performance, or if any of our preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party contract manufacturing organizations (CMOs) and contract research organizations, or CROs, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, business automobile, workers' compensation, clinical trials/products liability, cybersecurity liability, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. For example, although we maintain product liability insurance coverage that also covers our clinical trials, this insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

In addition, although we are dependent on certain key personnel, we do not have key person life insurance policies on any such individuals other than our Chief Executive Officer. While we maintain some life insurance coverage on our Chief Executive Officer, the insurance proceeds may not be sufficient to compensate for the adverse effects that we expect would arise from the loss of Fred Aslan, M.D., and the costs associated with recruiting a new Chief Executive Officer. Therefore, if any of our key personnel die or become disabled, the loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

Our cybersecurity risk management and strategy program consist of cybersecurity-related policies and procedures, industry standard technology solutions including antivirus, firewalls and monitoring tools, awareness training for all employees, periodic testing, insurance coverage and a cybersecurity incident response plan. We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property and confidential information that is proprietary, strategic or competitive in nature (Information Systems and Data).

Our information security function helps identify, assess and manage the Company's cybersecurity threats and risks, as well as identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example using manual tools, conducting scans of the threat environment, evaluating our industry's risk profile, evaluating threats reported to us, conducting internal and external audits, and conducting threat assessments for both internal and external threats.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example maintaining an incident response plan and policies, maintaining disaster recovery and business continuity plans, conducting risk assessments, encrypting certain data, maintaining network security controls, segregating data, maintaining access controls, monitoring systems, conducting periodic employee training, penetration testing, asset management tracking and disposal, physical security measures, and physical security controls.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, (1) Cybersecurity risk is addressed as a component of the Company's enterprise risk management program;(2) The security administrator works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact on our business; (3) Our management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk; and (4) We have a cybersecurity incident response plan to identify, assess, respond to, and inform escalating levels of management based on the nature and severity of such incidents.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity software providers. We also use third-party service providers to perform a variety of functions throughout our business, such as contract research organizations. We assess and manage cybersecurity risks associated with our use of these providers by obtaining third party reporting relating to reputation and litigation screening for these vendors.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see the section titled "Risk Factors" in Part I. Item 1A of this Annual Report on Form 10-K, including the risk factor titled "—Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or experience security breaches or other unauthorized or improper access."

Governance

The audit committee of our board of directors is responsible for oversight the Company's cybersecurity risk, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our information security and legal functions. Our head of information technology is responsible for integrating cybersecurity risk considerations into the Company's overall risk management strategy, communicating key priorities to relevant personnel, approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, reviewing security assessments and other security-related reports, and retaining assessors, consultants, auditors, or third parties in connection with the company's cybersecurity program. Although we design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This means that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business. It does not, however, mean that we meet any technical standards, specifications, or requirements.

Our cybersecurity incident response policy and plans are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances. The Director of Information Technology (IT) works with the Company's incident response team, which consists of members of IT, legal, compliance, human resources, and others as applicable) to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response policy and plans include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from management concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation. As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable, or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal data on our behalf. Our systems, servers, and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers, or otherwise impair our reputation and business. We may need to expend significant resources and make significant investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber attacks or successfully mitigating their effects. 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 future product candidates could be delayed.

Item 2. Properties.

Our principal office is located at 5505 Morehouse Drive, Suite 100, San Diego, California 92121, where we lease 51,621 square feet of space to house our principal office, research and process development laboratories and a cGMP manufacturing center to support our pipeline development and clinical trial supply. This lease will expire in 2029, subject to our option to an additional five-year term. We also have a lease agreement for an additional 13,405 square feet of office space in San Diego, California. We lease this space under a lease that terminates in June 2025. In addition, we have entered into a temporary license agreement for our occupation and use of an additional 11,960 square feet of office and laboratory space in San Diego, California. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

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

Our common stock has been listed on the Nasdaq Global Market under the symbol "ARTV" since July 19, 2024. Prior to this date, there was no public market for our common stock.

Holders of Common Stock

As of March 19, 2025, there were approximately 23 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

We have never declared or paid any dividends on our capital or common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws, and would depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K for information about our equity compensation plans which is incorporated by reference herein.

Recent Sales of Unregistered Securities

Common Stock Issued upon Conversion of Preferred Stock

In July 2024, immediately prior to the completion of our initial public offering (the IPO), 6,160,385 outstanding shares of convertible preferred stock converted into 6,160,385 shares of common stock. Immediately prior to the completion of the IPO, we filed an Amended and Restated Certificate of Incorporation, which authorized a total of 700,000,000 shares of common stock and 10,000,000 shares of preferred stock. Upon the filing of the Amended and Restated Certificate of Incorporation, 6,160,385 shares of our convertible preferred stock then outstanding were automatically converted into 6,160,385 shares of our common stock. Due to such conversion, the issuance of such shares of our common stock was exempt from registration under Section 3(a)(9) or Section 4(a)(2) of the Securities Act.

Common Stock Issued Upon Conversion of Simple Agreements for Future Equity (SAFEs)

In July 2024 and in connection with the closing of the IPO, we had in aggregate approximately $24.4 million outstanding under our SAFEs held by certain of our securityholders, which converted to 2,391,418 shares of our common stock, based on the IPO price of $12.00 per share (IPO Price), at a 15% discount to the IPO Price.

Use of Proceeds

On July 22, 2024, we completed our IPO pursuant to which we issued and sold an aggregate of 13,920,000 shares of our common stock, at the IPO Price. In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,088,000 shares of common stock at the public offering price, less underwriting discounts and commissions (Overallotment Option). On July 25, 2024, the underwriters exercised in-part their Overallotment Option and purchased 1,000,000 shares of our common stock. The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-280568), which were declared effective by the SEC on July 18, 2024. Jefferies LLC, TD Cowen and Cantor Fitzgerald & Co. acted as joint book-running managers for the IPO. Wedbush PacGrow and Needham & Company acted as co-lead managers for the IPO. Shares of our common stock began trading on The Nasdaq Global Market on July 19, 2024.

We received gross proceeds from our IPO of approximately $179.0 million, which resulted in net proceeds of approximately $162.3 million, after deducting underwriting discounts and commissions and other offering expenses payable by us of approximately $16.7 million. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 22, 2024.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections of this Annual Report on Form 10-K entitled "Special Note Regarding Forward-Looking Statements" and "Risk Factors," under Part I, Item 1A.

Overview

We are a clinical-stage biotechnology company focused on developing natural killer (NK) cell-based therapies for patients suffering from devastating autoimmune diseases and cancers. Our product candidates are derived from donor cells (allogeneic) rather than a patient's own cells (autologous) and are pre-manufactured, stored frozen and ready to ship to a patient's treatment location, making them what we believe to be "off-the-shelf." Our lead product candidate, AlloNK, is a non-genetically modified, cryopreserved NK cell therapy being evaluated in combination with B-cell targeted monoclonal antibodies (mAbs) in an ongoing Phase 1/1b trial in systemic lupus erythematosus (SLE) with or without lupus nephritis (LN) and a basket investigator-initiated trial (IIT) in multiple autoimmune indications. Seminal peer-reviewed clinical studies using autologous CD19 chimeric antigen receptor (CAR) T-cell therapy (auto-CAR-T) for the treatment of autoimmune diseases have demonstrated that deep B-cell depletion in the periphery and in the lymphoid tissue can lead to drug free disease remission. We have already demonstrated that AlloNK in combination with rituximab was able to drive deep B-cell depletion in the periphery and observed complete responses (CRs) in heavily pre-treated patients naïve to auto-CAR-T in our ongoing Phase 1/2 clinical trial in patients with relapsed or refractory B-cell non-Hodgkin lymphoma (B-NHL). We believe the preliminary results from our Phase 1/2 clinical trial evaluating AlloNK in combination with rituximab in patients with B-NHL provide a readthrough to autoimmune disease because efficacy in both diseases appears to be accomplished with a shared mechanism of action involving B-cell depletion in the periphery and in the lymphoid tissues, followed by an immunological reset and B-cell reconstitution. We expect to report initial data on autoimmune indications from at least one of our Phase 1/1b trial or the basket IIT in the first half of 2025.

We commenced our operations in 2019 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, establishing and engaging in collaborations, conducting research and development, advancing and scaling up product candidate manufacturing, establishing cold chain delivery logistics, establishing and protecting our intellectual property portfolio and providing general and administrative support for these activities. From our inception through December 31, 2024, we have raised aggregate gross proceeds of $8.0 million from the issuance and sale of convertible promissory notes, $70.0 million from our Series A convertible preferred stock financings, $120.0 million from our Series B convertible preferred stock financing and $24.4 million from our SAFEs. Additionally, in July 2024, we closed on our IPO, in which we issued and sold 13,920,000 shares of common stock at a public offering price of $12.00 per share. We also sold an additional 1,000,000 shares of common stock upon the partial exercise of the underwriters' purchase option. The aggregate net proceeds of the IPO, inclusive of the partial exercise of the underwriters' purchase option and after deducting underwriting discounts, commissions, and offering expenses, was $162.3 million.

We have incurred significant operating losses since the commencement of our operations. We have never generated any revenue from product sales and do not expect to generate any revenues from product sales unless and until we successfully complete development of and obtain regulatory approval for our product candidates, which will not be for several years, if ever. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We have incurred a net loss of $65.4 million and $28.7 million during the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $246.7 million, cash, cash equivalents and investments of $185.4 million. We expect to continue to incur significant losses for the foreseeable

future as we advance our current and future product candidates through preclinical and clinical development, continue to build our operations and transition to operating as a public company. Accordingly, 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 or debt financings or other capital sources, which may include our existing and any future strategic collaborations and other strategic arrangements with third parties. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. 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 additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or 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 capital or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs 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.

The manufacturing of our cell therapy products is novel and complex, and we have invested substantial resources to optimize the manufacturing process of our product candidates, including selection and optimization of cord blood units, establishing cold chain supply logistics and leveraging the current Good Manufacturing Practices (cGMP) manufacturing facility of GC Cell Corporation (GC Cell) to expand NK cells and create our product candidates. We also currently operate manufacturing facilities at our leased facility in San Diego, California to support NK and CAR-NK cell production for our pipeline development and clinical trial (and potentially commercial) supply. We also currently rely on other third-parties to ship and store our cord blood units and drug product lots, viral vectors and master and working feeder cell banks, as well as other components used in the manufacturing process for our product candidates, and we expect to continue to do so to meet our preclinical, clinical, and potential commercial activities. We expect that we and GC Cell will be capable of providing and processing sufficient quantities of our product candidates to meet anticipated clinical trial demands cost-effectively. However, any disruption in the supply or manufacture of our product candidates could result in delays in our preclinical studies and clinical trials and increase the costs of our research and development activities. We plan to continue to invest in our manufacturing capability and cryopreservation techniques to continuously improve our production and supply chain capabilities over time.

Collaboration and License Agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see the section titled “Business—Collaboration and License Agreements.”

GC Cell and Related Agreements

We have entered into several agreements with GC Cell and related entities concerning our NK cell therapy platform and manufacturing of our core products, as described below.

Option and License Agreement with GC Cell

In September 2019, we entered into an option and license agreement with GC Cell, formerly Green Cross Cell Corporation, as amended in June 2020 and February 2022 (the Core Agreement). Under the Core Agreement, GC Cell granted us an exclusive, royalty-bearing license, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell relating to non-genetically modified and genetically modified NK cells, and culturing, engineering, manufacturing thereof, to research, develop, manufacture, and commercialize NK cell pharmaceutical products anywhere in the world except for Asia, Australia, and New Zealand (the Artiva Territory). GC Cell retained rights under the license to allow it and its affiliates to perform obligations under the Core Agreement and other agreements between us and them.

Under the Core Agreement, GC Cell agreed to conduct a discovery, research, preclinical development, and manufacturing program under a plan approved by a Joint Steering Committee (the JSC), to generate and identify product candidates for nomination as option candidates. GC Cell will bear all costs for its work under the R&D Plan, except that Artiva will bear all costs for completing Investigational New Drug (IND) application-enabling activities performed by GC Cell on behalf of Artiva, other than certain efficacy studies.

For each product candidate determined by the JSC to be an option candidate, we have an exclusive option under the Core Agreement to obtain an exclusive, sublicensable license to research, develop, manufacture and commercialize such candidate in the Artiva Territory for any therapeutic, prophylactic or diagnostic uses in humans, on economic terms to be determined in good faith by the parties. GC Cell retains exclusive rights to the licensed technology in Asia, Australia, and New Zealand, though we have the right to request, and GC Cell has agreed to consider in good faith, inclusion of Australia, New Zealand and/or specific countries in Asia in the Artiva Territory on a product-by-product basis. If we elect not to exercise the option with respect to a particular option candidate, GC Cell retains the right to continue development of such candidate. As of December 31, 2024, we have exercised our rights to license four option candidates, including AlloNK (AB-101), AB-201 and AB-205, as described below.

We have control over and will bear the costs of the development, regulatory, manufacturing and commercialization activities relating to the option candidates for which we have exercised our option, each a licensed product. Accordingly, we have certain diligence obligations and must use commercially reasonable efforts to develop and seek regulatory approval for each licensed product in at least one indication in the United States and the European Union, and following regulatory approval in a country, to commercialize such licensed product in at least one indication in such country. The Core Agreement provides that we have the right to engage GC Cell or its appropriate affiliate to provide research and manufacturing services for the licensed products being developed by us in the Artiva Territory under separately executed service agreements.

Under the Core Agreement, we are obligated to pay a low single-digit percentage royalty on net sales of any licensed products, the manufacture, use or sale of which is claimed by or uses any Core IP. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. We also have the exclusive option to extend our license to the Core IP to be worldwide with respect to products originated from us in exchange for a specified increase in the applicable royalty. GC Cell is also obligated to pay us a royalty at a rate equal to 50% of the royalty payable by us for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property. As of December 31, 2024, we have not recognized any net sales royalties under this agreement.

AB-101 Selected Product License Agreement

In November 2019, we entered into a license agreement with GC Cell for our AB-101 product candidate, as amended in February 2022 (the AB-101 Agreement). AB-101 is the first product for which we exercised our option under the Core Agreement. Under the AB-101 Agreement, GC Cell granted us an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture and commercialize AB-101.

Under the AB-101 Agreement, we are obligated to pay tiered royalties in the low-mid to high single-digit percentage range on annual net sales of any licensed AB-101 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-101 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. We are also obligated to make milestone payments to GC Cell of: (1) up to $22.0 million upon the first achievement of certain development milestones; and (2) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay us a royalty at a rate equal to 50% of the royalty payable by us for such product in the Artiva Territory on net sales outside the Artiva Territory of any

licensed AB-101 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property. As of December 31, 2024, we have not recognized any net sales royalties or milestones under this agreement.

AB-201 Selected Product License Agreement

In October 2020, we entered into a license agreement with GC Cell for our AB-201 product candidate, as amended in February 2022 (the AB-201 Agreement). AB-201 is the second product for which we exercised our option under the Core Agreement. Under the AB-201 Agreement, GC Cell granted us an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture, and commercialize AB-201.

Under the AB-201 Agreement, we are obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-201 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-201 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. We are also obligated to make milestone payments to GC Cell of: (1) up to $25.0 million upon the first achievement of certain development milestones; and (2) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay us a royalty at a rate equal to 50% of the royalty payable by us for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-201 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property.

In September 2023, we entered into an amendment to the AB-201 Agreement (the Amended AB-201 Agreement). This amendment granted back to GC Cell an exclusive, royalty and milestone bearing license to all information and patents controlled by us that relate specifically to the research, development, manufacture and use of AB-201, to be used outside of the Artiva Territory. Under the Amended AB-201 Agreement, we will receive tiered royalties in the low single-digit percentage range on annual GC Cell net sales of AB-201 outside of the Artiva Territory. The royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of AB-201 outside of the Artiva Territory and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. We will also receive milestone payments upon achievement of certain development milestones, totaling $1.8 million. In December 2023, GC Cell achieved the first regulatory milestone under the Amended AB-201 Agreement for first IND acceptance for AB-201 outside the Artiva Territory.

License and development support-related revenue recognized in the statements of operations and comprehensive loss, related to GC Cell's development support activities under the Amended AB-201 Agreement, was $0.3 million and $0.6 million during the years ended December 31, 2024 and 2023, respectively.

AB-205 Selected Product License Agreement

In December 2022, we entered into a license agreement with GC Cell for its AB-205 product candidate (the AB-205 Agreement). AB-205 is the fourth product for which we exercised our option under the Core Agreement. Under the AB-205 Agreement, GC Cell granted us an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture and commercialize AB-205.

Under the AB-205 Agreement, we are obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-205 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-205 product and continuing until the later of (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a

licensed product in that country. Upon our election to proceed with clinical development of AB-205 (prior to which we may not make, use or sell AB-205 for clinical development purposes), we are obligated to pay a one-time payment of $2.5 million to GC Cell. Thereafter, we are also obligated to make milestone payments to GC Cell of: (i) up to $29.5 million upon the first achievement of certain development milestones, excluding any payments for the Development Cost Share as defined in the AB-205 Agreement; and (ii) up to $28.0 million upon the first achievement of certain sales milestones. As of December 31, 2024, we have not recognized any net sales royalties or milestones under this agreement.

Total reimbursements for development costs invoiced to GC Cell in connection with the AB-205 License Agreement were $0.1 million and $1.6 million for the years ended December 31, 2024 and 2023, respectively. Through December 31, 2024, we received $1.7 million in payments from GC Cell.

Research Services Agreement with GC Cell

As contemplated by the Core Agreement, in August 2020 we entered into the GC Cell Research Services Agreement, as amended in February 2022, under which GC Cell agreed to provide research services in support of the research and development of one or more of the products we have licensed from GC Cell. The Agreement provides that the parties will agree to specific projects as work orders under the GC Cell Research Services Agreement. Each work order shall set forth, upon terms mutually agreeable to GC Cell and us, the specific services to be performed by GC Cell, the timeline and schedule for the performance of the services, and the compensation to be paid by us to GC Cell for the provision of such services, as well as any other relevant terms and conditions.

Master Manufacturing Agreement with GC Cell

In March 2020, we entered into a Master Agreement for Manufacturing Services (the Manufacturing Agreement) with GC Cell, under which GC Cell agreed to manufacture specified products under individual work orders for use in our Phase 1 and Phase 2 clinical trials. Each work order will contain an estimated budget of service fees and out-of-pocket costs to be incurred in the performance of services under the agreement and the work order, as well as additional terms and conditions relating to the estimated budget. We will own all results and data generated by GC Cell under the Manufacturing Agreement.

Merck Exclusive License and Collaboration Agreement

In January 2021, we entered into the Exclusive License and Research Collaboration Agreement (the Merck Collaboration Agreement) with Merck Sharp & Dohme Corp. (Merck) for the discovery, development, manufacture and commercialization of CAR-NK cells that target certain solid tumor antigens. Merck paid us $30.0 million upfront for two target programs under the Merck Collaboration Agreement. We are also eligible to receive additional payments for achieving certain development, regulatory approval and sales milestones, as well as royalties on net sales. In addition, we will be reimbursed for the conduct of each research program, including external research costs and manufacture and supply of clinical material for Phase 1 clinical trials.

Concurrent with entering into the Merck Collaboration Agreement, we also entered into an agreement with GC Cell to obtain exclusive, worldwide rights to GC Cell's CAR-NK technology with respect to the licensed products and to engage GC Cell to perform services in support of the research programs (the Partnered Program License Agreement). We have agreed to reimburse GC Cell for research and development services as these services are provided. Artiva is required to pay GC Cell 100% of regulatory milestones, sales milestones and royalty payments received by Merck relating to products in Asia, Australia, and New Zealand and 50% of upfront payments, license fees, regulatory milestones, sales milestones and royalty payments received by Merck relating to products in all other territories.

In October 2023, the Merck Collaboration Agreement and development thereunder was terminated by Merck.

Affimed Collaboration Agreement

On November 1, 2022, we entered into a strategic collaboration agreement with Affimed GmbH, a subsidiary of Affimed N.V. for the clinical development and commercialization of a combination therapy, for any uses in humans or animals, comprising Affimed's product consisting of an innate cell engager referred to as "AFM13" our product containing an NK cell referred to as AB-101. While the collaboration is initially limited to the United States, the parties will, upon Affimed's request, in good faith discuss an expansion to certain other territories.

We have granted Affimed, with respect to the development of the combination therapy an exclusive, and with respect to the promotion of the combination therapy under the Affimed Collaboration Agreement a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free and non-sublicensable (with certain exceptions) license under relevant patents and know-how. Affimed has granted us a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free license and non-sublicensable (with certain exceptions) license under relevant Affimed patents and know-how for use in the clinical development of the combination therapy under the Affimed Collaboration Agreement.

The financial terms of the Affimed Collaboration Agreement provides that Affimed shall be responsible for all costs associated with the development of the combination therapy (including all clinical trial costs), except that Affimed and we shall each bear 50% of the costs and expenses incurred in connection with the performance of any confirmatory combination therapy clinical trial required by the FDA. We shall be solely responsible for all costs incurred by us for the supply of AB-101 and IL-2 product used in the clinical trials for the combination therapy, and for carrying out activities assigned to it under the agreed development plan. In addition, under the Affimed Collaboration Agreement, the parties agree to make payments to each other to achieve a proportion of 67%/33% (Affimed/Company) of revenues generated by both parties from commercial sales of each party's product as part of the combination therapy.

Expenses incurred in connection with the Affimed Collaboration Agreement were $0.1 million and $0.9 million during the years ended December 31, 2024 and 2023, respectively.

Components of Results of Operations

Collaboration Revenue

As of December 31, 2024, we have not generated any revenues from product sales or royalties. Our revenues have been derived from the Exclusive License and Research Collaboration Agreement (the Merck Collaboration Agreement) with Merck Sharp & Dohme Corp. (Merck) and a license agreement with GC Cell for our AB-201 product candidate, as amended in February 2022 and September 2023 (the AB-201 Agreement).

In January 2021, we entered into the Merck Collaboration Agreement which was subsequently terminated in October 2023, pursuant to which we received an upfront, non-refundable and non-creditable payment of $30.0 million for two target programs, with an additional $15.0 million payable by Merck if we and Merck agreed upon a third collaboration target.

Additionally, we were entitled to be reimbursed for the conduct of each research program, including external research costs and manufacture and supply of clinical materials for Phase 1 clinical trials, up to $14.0 million per program.

We concluded that Merck represented a customer and in accordance with Accounting Standards Codification (ASC) 606, we determined that the initial transaction price under the Merck Collaboration Agreement equals $58.0 million, consisting of the upfront, non-refundable and non-creditable payment of $30.0 million and the aggregate estimated research and development fees of $28.0 million. The initial transaction price was allocated evenly to each of the two product targets. In addition, we identified our performance obligations under the Merck Collaboration Agreement, including our grant to Merck of a license to certain of our intellectual property subject to certain conditions, our conduct of research services, and our participation in a joint research committee. We determined that all performance obligations should be accounted for as one combined performance obligation for each target program, and that since no individual performance obligation is distinct, and that the combined performance

obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years which represents the combined terms for the research programs. Upon termination of the Merck Collaboration Agreement, we recognized the remaining portion of the upfront, non-refundable $30.0 million in revenue.

Collaboration revenues recognized under the Merck Collaboration Agreement were zero and $32.9 million for the years ended December 31, 2024 and 2023, respectively.

License and Development Support Revenue

License and development support-related revenues related to GC Cell's development support activities under the AB-201 Agreement were $0.3 million and $0.6 million during the years ended December 31, 2024 and 2023, respectively.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Our research and development expenses consist primarily of external and internal costs related to the development of product candidates.

External costs include:

•expenses incurred in connection with research, laboratory consumables and preclinical studies;

•expenses incurred in connection with conducting clinical trials including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with contract research organizations (CROs) other vendors or central laboratories and service providers engaged to conduct our trials;

•the cost of consultants engaged in research and development related services and the cost to manufacture cell therapy product candidates for use in our clinical trials and preclinical studies;

•costs related to regulatory compliance; and

•the cost of annual license fees.

Internal costs include:

•personnel-related expenses, including salaries and related benefits, travel and stock-based compensation expenses for personnel engaged in research and development functions; and

•facilities, depreciation, and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies.

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. We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. We do not track our internal research and development costs on a program-by-program basis because these costs are associated with multiple programs and, as such, are not separately classified.

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our development programs. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. However, we expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future.

General and Administrative

General and administrative expenses consist of personnel-related expenses, including salaries and related benefits, travel and stock-based compensation expenses for personnel engaged in executive, finance and other administrative functions. Other significant costs include facilities-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and insurance costs. Additionally, costs include 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. We expect that our general and administrative expenses will increase substantially for the foreseeable future to support our continued research and development activities, pre-commercial preparation activities for our product candidates, and, if any product candidate receives marketing approval, commercialization activities.

Interest Income

Interest income consists of interest on our money market funds and short-term investments.

Change in Fair Value of Simple Agreement for Future Equity

In 2023, we issued $24.4 million of SAFEs to various existing investors and related parties. The SAFEs are recorded as liabilities at fair value and remeasured at fair value at each reporting period. The change in fair value for the period is recorded in change in fair value of SAFEs in the statements of operations.

In connection with the closing of the IPO, the outstanding SAFEs converted into 2,391,418 shares of our common stock.

Other Income, Net

Other income, net consists primarily of realized gains and losses on short-term investments.

Income Taxes

We are subject to corporate U.S. federal and state income taxation. We estimate our income tax provision, including deferred tax assets and liabilities, based on management's judgment. We record a valuation allowance to reduce our deferred tax assets to the amounts that are more likely than not to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance. If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (in thousands)

	YEAR ENDED DECEMBER 31, 2024	2023	CHANGE
Revenue:			
Collaboration revenue	$ —	$ 32,923	$ (32,923)
License and development support revenue	251	569	(318)
Total revenue	251	33,492	(33,241)
Operating expenses:			
Research and development	50,328	50,251	77
General and administrative	17,205	13,912	3,293
Total operating expenses	67,533	64,163	3,370
Loss from operations	(67,282)	(30,671)	(36,611)
Other income, net:			
Interest income	5,349	2,535	2,814
Change in fair value of SAFEs	(3,597)	(707)	(2,890)
Other income, net	157	195	(38)
Total other income, net	1,909	2,023	(114)
Loss before provision for income taxes	(65,373)	(28,648)	(36,725)
Provision for income taxes	—	(72)	72
Net loss	$ (65,373)	$ (28,720)	$ (36,653)
Unrealized gain (loss) on investments	(437)	308	(745)
Comprehensive loss	$ (65,810)	$ (28,412)	$ (37,398)

Collaboration Revenue. Collaboration revenues were nil for the year ended December 31, 2024, compared to $32.9 million for the year ended December 31, 2023. The decrease was related to the $32.9 million in revenue pursuant to the Merck Collaboration Agreement which consisted of $26.5 million of recognition of revenue from the deferred up-front payment and $6.4 million in reimbursement revenues for the year ended December 31, 2023.

License and Development Support Revenue. License and development support revenues were $0.3 million for the year ended December 31, 2024, compared to $0.6 million for the year ended December 31, 2023. Revenues were related to the achievement of a research-related milestone in 2023 and development support activities under the AB-201 Agreement with GC Cell.

Research and Development Expenses. We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. We do not track our internal research and development costs on a program-by-program basis. The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2023 (in thousands):

	YEAR ENDED DECEMBER 31, 2024	2023
External research and development expense:		
AB-101	$ 19,978	$ 14,090
Other programs	330	3,797
Internal research and development expense:		
Personnel-related	20,050	19,650
Other	9,970	12,714
Total research and development expense	$ 50,328	$ 50,251

Research and development expenses were $50.3 million for the year ended December 31, 2024, compared to $50.3 million for the year ended December 31, 2023. The increase of $0.1 million was primarily due to a $2.4 million increase in external research and development expense, offset by a $2.3 million decrease in internal research and development expense. The $2.4 million increase in external research and development expense is primarily due to a $5.9 million increase in AB-101 costs related to product candidate development and clinical trials as we progressed towards the end of our clinical trial for the B-NHL program and commencement of our clinical trial on the AlloNK for SLE/LN program. The increase was offset by a $3.5 million decrease in other programs as we narrowed our research focus to our AB-101 programs. The $2.3 million decrease in internal research and development expense is primarily due to a $2.7 million decrease in operating costs associated with discovery activities that were discontinued in 2023, offset by a $0.4 million increase in personnel-related expenses due to increased headcount in 2024.

General and Administrative Expenses. General and administrative expenses were $17.2 million for the year ended December 31, 2024, compared to $13.9 million for the year ended December 31, 2023. The increase of $3.3 million was primarily comprised of a $1.5 million increase in personnel-related costs including a $1.3 million increase in administrative personnel expenses and a $0.2 million increase in non-cash stock-based compensation, in addition to a $1.8 million increase in other operational and legal costs.

Other Income, Net. Other income was $1.9 million for the year ended December 31, 2024, compared to other income of $2.0 million for the year ended December 31, 2023. The decrease of $0.1 million was primarily due to the $2.9 million change in fair value of SAFEs, which we entered into in late 2023, offset by a $2.8 million increase in interest income due to more favorable rates of return during 2024.

Provision for Income Taxes. The provision for income taxes was zero for the year ended December 31, 2024, compared to $0.1 million for the year ended December 31, 2023.

Unrealized Gain (Loss) on Investments. Unrealized loss on investments was $0.4 million for the year ended December 31, 2024, compared to an unrealized gain of $0.3 million for the year ended December 31, 2023. The decrease between periods of $0.7 million was primarily due to the change in fair value of investments.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses and negative cash flows from operations since our inception and expect to continue to incur significant and increasing operating losses for the foreseeable future. We have never generated any revenue from product sales and do not expect to generate any revenues from product sales unless and until we successfully complete development of and obtain regulatory approval for our product candidates, which will not be for several years, if ever. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. From our inception through December 31, 2024, we have raised aggregate gross proceeds of $401.4 million to fund our operations, comprised primarily from proceeds received from the IPO, including proceeds from the underwriters' partial exercise of their overallotment option, our issuance of convertible promissory notes, SAFEs and private placements of our convertible preferred stock. In February 2021, we received a $30.0 million up-front payment from Merck for our two target programs. In addition, as of December 31, 2024, we have received $9.9 million related to reimbursable research services from Merck. As of December 31, 2024, we had cash, cash equivalents and investments of $185.4 million, and an accumulated deficit of $246.7 million. Based on our current operating plans, we expect our existing cash, cash equivalents and investments will be sufficient to fund our planned operating expenses and capital expenditure requirements at least through the end of 2026. Our total future capital requirements will depend on many factors and is subject to the risks and uncertainties set forth in the section titled "Risk Factors."

Future Funding Requirements

We expect our expenses and capital requirements to increase significantly in connection with our ongoing activities, particularly as we advance our lead product candidates and other development programs, in addition to the costs associated with operating as a public company. Accordingly, beyond the net proceeds raised in the IPO (including the partial exercise of the underwriters' overallotment option), we will continue to require substantial additional funding to support our continuing operations.

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

•the initiation, type, number, scope, results, costs and timing of, our ongoing and planned clinical trials of AlloNK, preclinical studies, and initiation of clinical trials for future product candidates, including feedback received from regulatory authorities;

•the costs and timing of manufacturing for our product candidates, including the costs and timing of maintaining our own manufacturing facility, and commercial scale manufacturing if any product candidate is approved;

•the potential expansion of our current development programs to seek new indications;

•the costs, timing and outcome of regulatory review of current or future product candidates;

•the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;

•our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;

•the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel;

•the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;

•the timing and amount of the milestone or other payments we must make to current and future collaborators and licensors;

•the costs and timing of establishing or securing sales and marketing capabilities if current or future product candidate is approved in a region where we choose to commercialize the product on our own;

•our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;

•patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors; and

•costs associated with any products or technologies that we may in-license or acquire.

Until such time as we can generate substantial revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders 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 collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs, or product candidates or 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 or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs 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.

Cash Flows

Comparison of the Years Ended December 31, 2024, and 2023

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2024, and 2023 (in thousands):

	YEAR ENDED DECEMBER 31, 2024	2023
Net cash (used in) provided by:		
Operating activities	$ (55,032)	$ (47,430)
Investing activities	(120,463)	(25,975)
Financing activities	162,226	24,391
Net decrease in cash	$ (13,269)	$ (49,014)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2024, was $55.0 million, consisting primarily of our net loss incurred during the period of $65.4 million, partially offset by $10.7 million of non-cash charges. Non-cash charges consisted of $7.0 million in stock-based compensation expense, $3.6 million in change in fair value of SAFEs, $2.4 million in depreciation and amortization expense, and $2.3 million of accretion of discounts on short-term investments. Changes in operating assets and liabilities included a $2.0 million increase in prepaid expense and other current assets, a $1.6 million decrease in receivables, a $0.7 million decrease in accrued expenses, a $0.5 million increase in accounts payable, and a $0.3 million change in other net balance sheet assets and liabilities.

Net cash used in operating activities for the year ended December 31, 2023, was $47.4 million, consisting primarily of our net loss incurred during the period of $28.7 million, partially offset by $9.6 million of non-cash charges and $28.3 million of a net decrease in operating assets and liabilities. Non-cash charges consisted primarily of $7.1 million in stock-based compensation expense, $2.3 million in depreciation and amortization expense, $0.7 million in change in fair value of SAFEs and $0.5 million of accretion of discounts on short-term investments. The net change in operating assets and liabilities related primarily to a $26.5 million decrease in deferred revenue, a $1.2 million decrease in receivables, a $0.9 million decrease in accrued expenses, and a $0.4 million decrease in accounts payable, partially offset by decreases of $0.5 million in prepaid expenses and other current assets and $0.2 million of other balance sheet items.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2024, was $120.5 million related to $176.2 million of purchases of investments and $0.6 million of purchases of property and equipment, partially offset by $56.3 million in maturities of short-term investments.

Net cash used in investing activities for the year ended December 31, 2023, was $26.0 million related to $49.5 million of purchases of short-term investments and $3.3 million related to purchases of property and equipment, partially offset by $26.8 million in maturities of short-term investments.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024, was $162.2 million related to net cash proceeds received from the IPO.

Net cash provided by financing activities for the year ended December 31, 2023, was $24.4 million related to SAFE proceeds received.

Contractual Obligations and Commitments

In addition to ongoing capital needs to fund our ongoing operations, our material cash requirements include the following contractual and other obligations.

We lease certain office space in San Diego, California, under a non-cancelable operating lease, with a term through December 2025 (the Executive Drive Lease). The Executive Drive Lease commenced on December 23, 2019, with a six-year initial term and includes aggregate monthly payments to the lessor of approximately $2.8 million. The Executive Drive Lease also provides for rent abatements and scheduled increases in base rent. In connection with the lease, we made a one-time cash security deposit in the amount of $0.4 million, of which $0.2 million was refunded in October 2021 and the remaining $0.2 million is refundable at the end of the lease term and is included in long-term assets in the balance sheets. The Executive Drive Lease includes a renewal option, which includes an option to renew for five additional years. We will not exercise the option and, as such, is not reflected as part of the right of use asset and associated lease liabilities.

In June 2021, we entered into a lease agreement for corporate office and laboratory space in San Diego, California (the Morehouse Lease), which represented a portion of a new facility that was under construction. The Morehouse Lease includes multiple, successive commencement dates. The office and laboratory space commenced in the second quarter of 2022 and the third quarter of 2022 for the cGMP manufacturing center. The Morehouse Lease has an initial term of 88 months and includes aggregate monthly payments to the lessor of approximately $23.2 million with a rent escalation clause, and a tenant improvement allowance of $12.3 million. We are also required to maintain a cash security deposit in the form of an unconditional and irrevocable letter of credit of $0.2 million which must remain in place until the termination of the lease and is considered a non-current asset as of December 31, 2024. These obligations are further described in Note 11 to our financial statements appearing elsewhere in this this Annual Report.

In August 2022, we entered into a lease agreement to use designated laboratory and vivarium space in San Diego, California (the Explora Lease). The Explora Lease is accounted for as an operating lease and commenced in August 2022. The Explora Lease has an initial term of 36 months and includes aggregate monthly payments to the lessor of approximately $0.8 million with a rent escalation clause.

On July 22, 2022, we entered into a sublease (the Sublease Agreement) with Origis Operating Services, LLC, (the Sublessee), whereby we agreed to sublease to Sublessee all of the 13,405 rentable square feet of office space currently leased by us under the Executive Drive Lease. The sublease commenced on August 1, 2022, and has a term through December 31, 2025. The aggregate base rent is approximately $2.6 million commencing August 1, 2022. We record sublease income as a reduction of general and administrative expense. Upon execution of the Sublease Agreement, we received a cash security deposit of $0.1 million from the Sublessee which is recorded as other non-current liabilities in the balance sheets.

As of December 31, 2024, we have future remaining operating lease payments of $17.0 million relating to leases we have recognized in the balance sheets, of which $4.0 million is payable before December 31, 2025.

Under our collaboration agreements, we have milestone payment obligations that are contingent upon the achievement of specified development, regulatory and commercial sales milestones and are required to make certain royalty payments in connection with the sale of products developed under the agreement (see Note 8 to our financial statements included elsewhere in this Annual Report). As of December 31, 2024, we are unable to estimate the timing or likelihood of achieving the milestones or making future product sales.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses, and the disclosure of our contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements, each appearing elsewhere in this Annual Report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Under Collaboration Agreements

We recognize research and development revenue from the Merck Collaboration Agreement. Collaboration agreements typically contain multiple elements, or performance obligations, including technology licenses or options to obtain technology licenses, research and development services, and manufacturing services. Upon entering into a collaboration agreement, we are required to make the following judgments:

- *Identifying the performance obligations contained in the agreement.* Our assessment of what constitutes a separate performance obligation requires the application of judgment. Specifically, we have to identify which goods and services we are required to provide under the contract are distinct.

- *Determining the transaction price, including any variable consideration*. To determine the transaction price, we review the amount of consideration eligible to earn under the agreement. We do not typically include any payments that may be received in the future in the initial transaction price since the payments are typically not probable because they are contingent upon certain future events. We are required to reassess the total transaction price at each reporting period to determine if additional payments should be included in the transaction price that have subsequently become probable.

- *Allocating the transaction price to each of the performance obligations*. When we allocate the transaction price to more than one performance obligation, we make estimates of the relative stand-alone selling price of each performance obligation because we do not typically sell our goods or services on a stand-alone basis. The estimate of the relative stand-alone selling price requires us in some cases to make significant judgments. For example, when delivering a license at the start of an agreement, we use valuation methodologies, such as the relief from royalty method, to value the license. Under this method we are required to make estimates, including: future sales, royalties on future product sales, contractual milestones, expenses, income taxes and discount rates. Additionally, when estimating the selling price for research and development services, we make estimates, including: the number of internal hours to be spent on the services, the cost of work we and third parties will perform, and the cost of clinical trial material to be used.

The research and development revenue we recognize each period is comprised of amortization from upfront payments and reimbursements for research services. Each of these types of revenue requires us to make various judgments and estimates. In October 2023, the Merck Collaboration Agreement and development thereunder was terminated by Merck.

Research and Development Expenses and Accrued Research and Development Costs

We are required to estimate our expenses resulting from obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our financial statements by matching those expenses with the period in which services and

efforts are expended. We account for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities. We determine accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies, or other services being conducted.

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.

Fair Value of Simple Agreement for Future Equity

As described above, we have entered into SAFEs with various existing investors and related parties. The SAFEs granted investors with rights to participate in a future equity financing. The SAFEs have no maturity dates and bear no interest. The estimated fair value of the SAFEs is determined based on the aggregated, probability-weighted average of the outcomes of certain scenarios, including: (i) an equity financing, with conversion of the SAFEs into a number of shares of convertible preferred stock at the lower of the post-money valuation cap price of $48.25 and the discount price (lowest price of the standard convertible preferred stock sold in the equity financing multiplied by the specified discount rate of 85%); (ii) an initial public offering, with conversion of the SAFEs into a number of shares of common stock equal to the purchase amount of the SAFE divided by the discount price (the lower of (a) the price per share of common stock sold to the public by the underwriters in the initial public offering multiplied by the discount rate of 85% or (b) the post-money valuation cap price of $48.25); (iii) a liquidity event (change of control or direct listing) with mandatory conversion to common stock at the lower of the post-money valuation cap price of $48.25 and the discount price (price of the common stock multiplied by the discount rate of 85%); and (iv) a dissolution event, with SAFEs holders automatically entitled to receive cash payments equal to the purchase amount, prior to and in preference to any distribution of any assets or surplus funds to the holders of convertible preferred and common stock. The combined value of the probability-weighted average of those outcomes is then discounted back to each reporting period in which the SAFEs are outstanding, in each case based on a risk-adjusted discount rate estimated based on the implied interest rate using the changes in observed interest rates of corporate debt that we believe is appropriate for those probability-adjusted cash flows.

SAFEs are recorded as liabilities at fair value and remeasured at fair value at each reporting period. We record changes in fair value of all SAFEs in changes in fair value of SAFEs in the statements of operations and comprehensive loss. Debt issuance costs related to the SAFEs were recorded as general and administrative expenses in the statements of operations and comprehensive loss as incurred.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock options. We estimate the fair value of stock options on the date of grant using the Black-Scholes option pricing model and recognize the expense over the requisite service period of the awards, which is generally the vesting period, on a straight-line basis. We account for forfeitures when they occur and reverse any compensation cost previously recognized for awards for which the requisite service has not been completed, in the period that the award is forfeited.

The Black-Scholes option pricing model uses inputs which are highly subjective assumptions and generally requires significant judgment. These assumptions include:

- ***Fair Value of Common Stock***. See the subsection titled "—Common Stock Valuation" below for valuation methodologies used prior to the initial public offering (IPO). Since the IPO, the fair value of common stock is the closing stock price on the date of grant.
- ***Expected Term***. The expected term represents the period that the options granted are expected to be outstanding. We have limited historical stock option activity and therefore estimate the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term.

•***Expected Volatility***. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development, as there is limited stock price data available of our common stock since the IPO. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

•***Risk-Free Interest Rate***. The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options.

•***Expected Dividend Yield***. We have historically not declared or paid any dividends and do not currently expect to do so in the foreseeable future, and therefore have estimated the dividend yield to be zero.

See Note 9 to our financial statements included elsewhere in this Annual Report for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

Common Stock Valuation

We are required to estimate the fair value of the common stock underlying our stock-based awards when performing fair value calculations using the Black-Scholes option pricing model. Prior to the IPO, the fair value of the common stock underlying our stock-based awards was determined on each grant date by our board of directors or our compensation committee, with input from management, considering our most recently available third-party valuation of common shares. All options to purchase shares of our common stock were intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

Our determination of the value of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants (AICPA), Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation (the AICPA Practice Aid). In addition, our board of directors considered various objective and subjective factors to determine the fair value of our common stock, including:

•valuations of our common stock performed by independent third-party valuation specialists;

•the anticipated capital structure that will directly impact the value of the currently outstanding securities;

•our results of operations and financial position;

•the status of our research and development efforts;

•the composition of, and changes to, our management team and board of directors;

•the lack of liquidity of our common stock as a private company;

•our stage of development and business strategy and the material risks related to our business and industry;

•external market conditions affecting the life sciences and biotechnology industry sectors;

•U.S. and global economic conditions;

•the likelihood of achieving a liquidity event for the holders of our common stock, such as an IPO or a sale of our company, given prevailing market conditions; and

•the market value and volatility of comparable companies

The AICPA Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics.

In accordance with the AICPA Practice Aid, we considered the various methods for allocating the enterprise value to determine the fair value of our common stock at the valuation date. Under the option pricing method (OPM), shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The value of the common stock is inferred by analyzing these options. The probability weighted expected return method (PWERM) is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Based on our early stage of development and other relevant factors, we determined that an OPM method was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock for valuations performed prior to December 31, 2020. For valuations performed after that date and prior to December 31, 2022, we determined that a PWERM method was the most appropriate. Following the withdrawal of our related registration statement with the SEC on November 1, 2022, we determined that the OPM method was again the most appropriate method to determine the estimated fair value of our common stock for valuations performed after that date and prior to April 18, 2024. For the valuation performed on April 18, 2024 for stock options granted on May 2, 2024, we determined that a hybrid method that combines both OPM and PWERM was the most appropriate. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act). Under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. However, we may elect to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. We may take advantage of these exemptions up until the time that we are no longer an emerging growth company.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined by Rule 12b-2 of the Exchange Act because both the market value of our stock held by non-affiliates is less than $700 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. 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.

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

We are a smaller reporting company as defined in Item 10(f)(1) of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required pursuant to this item are incorporated by reference herein from the applicable information included in Item 15(a)(1) and (2) of this Annual Report on Form 10-K and are presented beginning on page F-1.

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

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are 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 by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Item 9B. Other Information.

Trading Arrangements

During the quarter ended December 31, 2024, no director or officer adopted or terminated any Rule 10b5-1 trading arrangement or any non-Rule 10b5-1 trading arrangement (as such terms are defined pursuant to 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.

We have adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics provides a framework for sound ethical business decisions and sets forth our expectations on a number of topics, including conflicts of interest, compliance with laws, use of our assets and business ethics. Our code of business conduct and ethics is available under the Corporate Governance section of our website at www.artivabio.com. If the Company ever were to amend or waive any provision of its code of business conduct and ethics that applies to the Company's principal executive officer, principal financial officer, principal accounting officer or any person performing similar functions, the Company intends to satisfy its disclosure obligations, if any, with respect to any such waiver or amendment by posting such information on its website set forth above rather than by filing a Current Report on Form 8-K. In the case of a waiver for an executive officer or a director, the disclosure required under applicable Nasdaq listing standards also will be made available on our website.

The remaining information required by this Item will be set forth in the sections headed "Nominees for Election to the Board of Directors" and "The Board of Directors and Certain Governance Matters" in the Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item will be set forth in the section headed "Executive Compensation" in the Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

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

The information required by this Item will be set forth in the section headed "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item will be set forth in the section headed "Certain Relationships and Related Person Transactions" in the Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be set forth in the section headed "Principal Accountant Fees and Services" in the Proxy Statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)

1.All financial statements.

The financial statements of Artiva Biotherapeutics, Inc., together with the report thereon of KPMG LLP, an independent registered public accounting firm, are included in this Annual Report on Form 10-K on the following pages:

Report of Independent Registered Public Accounting Firm (KPMG LLP, San Diego, California; PCAOB ID: 185	F-2
Balance Sheets	F-3
Statements of Operations and Comprehensive Loss	F-4
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7

2.Financial statement schedules.

All schedules have been omitted because the information required to be set forth therein is not applicable, not required or the information required is shown in the financial statements or notes thereto.

3.Exhibits

The following is a list of exhibits filed with this report or incorporated herein by reference.

Exhibit Index

Exhibit number	Description of document	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	7/22/2024	3.1	
3.2	Amended and Restated Bylaws.	S-1	6/28/2024	3.4	
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	7/15/2024	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated February 22, 2021, by and among the Registrant and certain of its stockholders.	S-1	6/28/2024	4.2	
4.3	Description of the Registrant's Capital Stock.				X
10.1+	Form of Indemnity Agreement, by and between the Registrant and its directors and officers.	S-1	6/28/2024	10.1	
10.2+	The Registrant's 2020 Equity Incentive Plan, as amended.	S-1	6/28/2024	10.2	
10.3+	Forms of Stock Option Grant Notice, Stock Option Grant Notice with Acceleration of Vesting, Option Agreement and Notice of Exercise under the Registrant's 2020 Equity Incentive Plan.	S-1	6/28/2024	10.3	
10.4+	The Registrant's 2024 Equity Incentive Plan	S-8	7/22/2024	99.3	
10.5+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Registrant's 2024 Equity Incentive Plan.	S-1/A	7/15/2024	10.5	
10.6+	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Registrant's 2024 Equity Incentive Plan.	S-1/A	7/15/2024	10.6	
10.7+	The Registrant's 2024 Employee Stock Purchase Plan.	S-8	7/22/2024	99.6	
10.8+	The Registrant's Non-Employee Director Compensation Policy.	S-1/A	7/15/2024	10.8	
10.9+	Executive Employment Agreement, dated December 14, 2020, as amended, by and between the Registrant and Fred Aslan, M.D.	S-1	6/28/2024	10.9	
10.10+	Employment Offer Letter, dated May 21, 2022, by and between the Registrant and Thorsten Graef, M.D., Ph.D.	S-1	6/28/2024	10.10	
10.11+	Employment Offer Letter, dated August 27, 2020, as amended, by and between the Registrant and Jennifer Bush.	S-1	6/28/2024	10.11	
10.12	Office Lease, dated June 12, 2019, by and between the Registrant and AAT La Jolla Commons, LLC (as successor-in-interest to HSPF La Jolla Commons I Investors LLC).	S-1	6/28/2024	10.12	
10.13^	Option and License Agreement, dated September 4, 2019, by and between the Registrant and GC Cell Corporation (f/k/a GC Lab Cell Corporation).	S-1	6/28/2024	10.13	
10.14	Amendment No. 1 to Option and License Agreement, dated June 23, 2020, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.14	

Exhibit number	Description of document	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.15^	Omnibus Amendment, dated February 3, 2022, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.15	
10.16^	Master Agreement for Manufacturing Services, dated March 16, 2020, by and between the Registrant and GC Cell Corporation (f/k/a GC Lab Cell Corporation).	S-1	6/28/2024	10.16	
10.17	Amendment No. 1 to Master Agreement for Manufacturing Services, dated June 16, 2020, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.17	
10.18^	Master Research Services Agreement, dated August 3, 2020, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.18	
10.19^	Selected Product License Agreement (AB-101), dated November 21, 2019, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.19	
10.20^	Selected Product License Agreement (AB-201), dated September 29, 2020, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.20	
10.21^	Amendment to Selected Product License Agreement (AB-201), dated September 6, 2023, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.21	
10.22	Lease Agreement, dated June 16, 2021, by and between the Registrant and ARE-SD Region No. 66, LLC.	S-1	6/28/2024	10.22	
10.23	License Agreement, dated June 16, 2021, by and between the Registrant and ARE-SD Region No. 37, LLC.	S-1	6/28/2024	10.23	
10.24	First Amendment to License Agreement, dated May 9, 2022, by and between the Registrant and ARE-SD Region No. 37, LLC.	S-1	6/28/2024	10.24	
10.25^	Selected Product License Agreement (CD5), dated December 20, 2022, by and between the Registrant and GC Cell Corporation.	S-1	6/28/2024	10.25	
10.26^	Collaboration Agreement, dated November 1, 2022, by and between the Registrant and Affimed GmbH.	S-1	6/28/2024	10.26	
10.27	Amendment No. 1 to Collaboration Agreement, dated November 14, 2022, by and between the Registrant and Affimed GmbH.	S-1	6/28/2024	10.27	
10.28	Amendment No. 2 to Collaboration Agreement, dated June 30, 2023, by and between the Registrant and Affimed GmbH.	S-1	6/28/2024	10.28	
10.29+	Employment Offer Letter, dated December 7, 2021, by and between the Registrant and Christopher P. Horan.	S-1	6/28/2024	10.29	
10.30+	Employment Offer Letter, dated April 15, 2024, by and between the Registrant and Neha Krishnamohan.	S-1	6/28/2024	10.36	
10.31+	Employment Offer Letter, dated September 17, 2020, by and between the Registrant and Heather Raymon, Ph.D.	S-1	6/28/2024	10.37	
10.32+	Consulting Agreement dated November 1, 2023, as amended, by and between the Registrant and Diego Miralles, M.D.	S-1	6/28/2024	10.38	

Exhibit number	Description of document	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
19.1	Insider Trading Policy				X
24.1	Power of Attorney (included on the signature page).				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97	Incentive Compensation Recoupment Policy				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema With embedded Linkbase Documents Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

+ Indicates management contract or compensatory plan
* 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.
^ Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Registrant has determined that the information is not material and is the type that the Registrant treats as private or confidential

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ARTIVA BIOTHERAPEUTICS, INC.

Date: March 24, 2025

By: /s/ Fred Aslan, M.D.
Fred Aslan, M.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Fred Aslan, M.D. and Neha Krishnamohan and each of them, as his or her true and lawful attorneys-in-fact and agents, and each of them, with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Fred Aslan, M.D. **Fred Aslan, M.D.**	President and Chief Executive Officer (Principal Executive Officer)	March 24, 2025
/s/ Neha Krishnamohan **Neha Krishnamohan**	Chief Financial Officer and EVP, Corporate Development (Principal Financial and Accounting Officer)	March 24, 2025
/s/ Brian Daniels, M.D. **Brian Daniels, M.D.**	Director and Board Chair	March 24, 2025
/s/ Laura Bessen, M.D. **Laura Bessen, M.D.**	Director	March 24, 2025
/s/ Elizabeth Hougen **Elizabeth Hougen**	Director	March 24, 2025
/s/ Yong-Jun Huh **Yong-Jun Huh**	Director	March 24, 2025
/s/ Diego Miralles, M.D. **Diego Miralles, M.D.**	Director	March 24, 2025
/s/ Alison Moore **Alison Moore**	Director	March 24, 2025
/s/ Laura Stoppel, Ph.D. **Laura Stoppel, Ph.D.**	Director	March 24, 2025
/s/ Daniel Baker, M.D. **Daniel Baker, M.D.**	Director	March 24, 2025

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Artiva Biotherapeutics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Artiva Biotherapeutics, Inc. (the Company) as of December 31, 2024 and 2023, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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/ KPMG LLP

We have served as the Company's auditor since 2020.

San Diego, California
March 24, 2025

ARTIVA BIOTHERAPEUTICS, INC.

Balance Sheets
(in thousands, except share and par value data)

	AS OF	
	DECEMBER 31, 2024	DECEMBER 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 40,235	$ 53,504
Short-term investments	145,193	23,467
Accounts receivable (including related party amounts of $0 and $569, respectively)	—	1,034
Other receivables (including related party amounts of $0 and $607, respectively)	146	724
Prepaid expenses and other current assets	3,057	1,092
Total current assets	188,631	79,821
Restricted cash	258	258
Property and equipment, net	6,370	8,096
Operating lease right-of-use assets	13,794	16,547
Financing lease right-of-use asset	261	—
Other long-term assets	267	392
Total assets	$ 209,581	$ 105,114
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable (including related party amounts of $276 and $199, respectively)	$ 1,121	$ 614
Accrued expenses (including related party amounts of $713 and $2,161, respectively)	7,392	8,017
Current portion of operating lease liabilities	3,618	3,596
Current portion of financing lease liability	122	—
Total current liabilities	12,253	12,227
Operating lease liabilities, net of current portion	10,570	13,316
Financing lease liability, net of current portion	44	—
Simple agreements for future equity ("SAFEs") (including related party amounts of $0 and $20,315, respectively)	—	25,100
Other non-current liabilities	73	73
Total liabilities	22,940	50,716
Commitments and contingencies (Note 11)		
Series A convertible preferred stock, $0.0001 par value; zero and 16,110,463 shares authorized as of December 31, 2024 and December 31, 2023, respectively; zero and 3,673,148 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; zero and $80,552 aggregate liquidation preference at December 31, 2024 and December 31, 2023, respectively	—	96,767
Series B convertible preferred stock, $0.0001 par value; zero and 10,909,091 shares authorized as of December 31, 2024 and December 31, 2023, respectively; zero and 2,487,237 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; zero and $120,000 aggregate liquidation preference at December 31, 2024 and December 31, 2023, respectively	—	119,646
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and zero shares authorized at December 31, 2024 and December 31, 2023 respectively; zero shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 700,000,000 and 38,998,588 shares authorized at December 31, 2024 and December 31, 2023, respectively; 24,291,607 and 809,758 shares issued and outstanding at December 31, 2024 and December 31, 2023	3	—
Additional paid-in capital	433,451	18,988
Accumulated other comprehensive gain (loss)	(129)	308
Accumulated deficit	(246,684)	(181,311)
Total stockholders' equity (deficit)	186,641	(162,015)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 209,581	$ 105,114

See accompanying notes to financial statements

ARTIVA BIOTHERAPEUTICS, INC.

Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	YEAR ENDED DECEMBER 31,	
	2024	**2023**
Revenue:		
Collaboration revenue	$ —	$ 32,923
License and development support revenue (including related party amounts of $251 and $569, respectively)	251	569
Total revenue	251	33,492
Operating expenses:		
Research and development (including related party amounts of $3,168 and $3,832, respectively)	50,328	50,251
General and administrative	17,205	13,912
Total operating expenses	67,533	64,163
Loss from operations	(67,282)	(30,671)
Other income, net:		
Interest income	5,349	2,535
Change in fair value of SAFEs (including related party amounts of $2,911 and $573, respectively)	(3,597)	(707)
Other income, net	157	195
Total other income, net	1,909	2,023
Loss before provision for income taxes	(65,373)	(28,648)
Provision for income taxes	—	(72)
Net loss	$ (65,373)	$ (28,720)
Net loss per share, basic and diluted	$ (5.81)	$ (35.78)
Weighted-average common shares outstanding, basic and diluted	11,258,851	802,747
Comprehensive loss:		
Net loss	$ (65,373)	$ (28,720)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments	(437)	308
Comprehensive loss	$ (65,810)	$ (28,412)

See accompanying notes to financial statements

ARTIVA BIOTHERAPEUTICS, INC.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	SERIES A CONVERTIBLE PREFERRED STOCK		SERIES B CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	GAIN (LOSS)	DEFICIT	(DEFICIT)
Balance at December 31, 2022	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**792,991**	**$ —**	**$ 11,895**	**$ —**	**$ (152,591)**	**$ (140,696)**
Exercise of stock options	—	—	—	—	1,948	—	10	—	—	10
Vesting of shares of common stock subject to repurchase, including early exercise	—	—	—	—	14,819	—	30		—	30
Stock-based compensation expense	—	—	—	—	—	—	7,053	—	—	7,053
Unrealized gain on investments	—	—	—	—	—	—	—	308	—	308
Net loss	—	—	—	—	—	—	—	—	(28,720)	(28,720)
Balance at December 31, 2023	**3,673,148**	**$ 96,767**	**2,487,237**	**$ 119,646**	**809,758**	**$ —**	**$ 18,988**	**$ 308**	**$ (181,311)**	**$ (162,015)**
Conversion of preferred stock into common stock upon completion of initial public offering (IPO)	(3,673,148)	(96,767)	(2,487,237)	(119,646)	6,160,385	1	216,412			216,413
Exercise of stock options	—	—	—	—	10,046	—	51	—	—	51
Issuance of common shares in connection with IPO, net of offering costs	—	—	—	—	14,920,000	2	162,323	—	—	162,325
Issuance of common shares upon the conversion of SAFE notes	—	—	—	—	2,391,418	—	28,697	—	—	28,697
Stock-based compensation expense	—	—	—	—	—	—	6,980	—	—	6,980
Unrealized loss on investments	—	—	—	—	—	—	—	(437)	—	(437)
Net loss	—	—	—	—	—	—	—	—	(65,373)	(65,373)
Balance at December 31, 2024	**—**	**$ —**	**—**	**$ —**	**24,291,607**	**$ 3**	**$ 433,451**	**$ (129)**	**$ (246,684)**	**$ 186,641**

See accompanying notes to financial statements

ARTIVA BIOTHERAPEUTICS, INC.

Statements of Cash Flows
(in thousands)

	YEAR ENDED DECEMBER 31, 2024	2023
Operating activities:		
Net loss	$ (65,373)	$ (28,720)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,431	2,266
Stock-based compensation	6,980	7,053
Change in fair value of SAFEs (including related party amounts of $2,911 and $573, respectively)	3,597	707
Accretion of discounts and amortization of premiums on investments, net	(2,342)	(456)
Changes in operating assets and liabilities:		
Accounts receivable (including related party amounts of $569 and $(569), respectively)	1,034	(510)
Other receivables (including related party amounts of $607 and $(607), respectively)	578	(724)
Prepaid expenses and other current assets	(1,965)	516
Other long-term assets	125	139
Accounts payable (including related party amounts of $76 and $51, respectively)	519	(408)
Accrued expenses (including related party amounts of $(1,447) and $(971), respectively)	(659)	(912)
Operating lease right-of-use asset and lease liabilities, net	43	145
Deferred revenue	—	(26,526)
Net cash used in operating activities	(55,032)	(47,430)
Investing activities:		
Purchases of property and equipment	(642)	(3,258)
Purchases of short-term investments	(176,171)	(49,517)
Maturities of short-term investments	56,350	26,800
Net cash used in investing activities	(120,463)	(25,975)
Financing activities:		
Proceeds from issuance of common stock, net of commissions	166,507	—
Proceeds from issuance of simple agreements for future equity (including related party amounts of $0 and $19,742, respectively)	—	24,393
Proceeds from exercise of stock options	51	10
Payments on finance leases	(149)	—
Cash paid in connection with IPO offering costs	(4,183)	—
Repurchase of restricted stock	—	(12)
Net cash provided by financing activities	162,226	24,391
Net decrease in cash, cash equivalents and restricted cash	(13,269)	(49,014)
Cash, cash equivalents and restricted cash at beginning of period	53,762	102,776
Cash, cash equivalents and restricted cash at end of period	$ 40,493	$ 53,762
Reconciliation of cash, cash equivalents and restricted cash to the balance sheet:		
Cash and cash equivalents	$ 40,235	$ 53,504
Restricted cash	258	258
Total cash, cash equivalents and restricted cash	$ 40,493	$ 53,762
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes	$ —	$ 83
Supplemental disclosures of noncash activities:		
Property and equipment purchases in accounts payable and accrued liabilities	$ 57	$ 18
Conversion of SAFE notes to common stock	$ 28,697	$ —
Conversion of preferred stock to common stock	$ 216,413	$ —
Non-cash additions to financing leases	$ 241	$ —

See accompanying notes to financial statements

ARTIVA BIOTHERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Organization, Liquidity and Basis of Presentation

Organization

Artiva Biotherapeutics, Inc. (the "Company") was incorporated in the State of Delaware on February 14, 2019. The Company is a biopharmaceutical company focused on developing off-the-shelf, allogeneic, natural killer ("NK") cell-based therapies that are effective, safe and accessible for patients with devastating autoimmune diseases and cancers.

From its inception to December 31, 2024, the Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, raising capital, establishing and engaging in collaborations, performing research and development, advancing and scaling up product candidate manufacturing, establishing cold chain delivery logistics, establishing and protecting its intellectual property portfolio, and providing general and administrative support for these activities.

Reverse Stock Split

On July 12, 2024, the Company effected a 1-for-4.386 reverse stock split of its common stock and convertible preferred stock. The par value and the authorized shares of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock split. These accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

Initial Public Offering

On July 22, 2024, the Company completed its Initial Public Offering (the "IPO"), pursuant to which it issued and sold 13,920,000 shares of common stock at a public offering price of $12.00 per share. The aggregate gross proceeds of the IPO were $167.0 million before underwriter discounts and commissions, fees, and expenses of $15.9 million, for net proceeds from the IPO of $151.1 million. On July 25, 2024, the underwriters partially exercised their 30-day option and purchased an additional 1,000,000 shares of the Company's common stock at the IPO price, upon which the Company received additional gross proceeds of $12.0 million before commissions of $0.8 million, for net proceeds of approximately $11.2 million. The aggregate net proceeds of the IPO was $162.3 million (the "IPO Proceeds"). All underwriter discounts and commissions, fees, and expenses, including deferred offering costs have been charged to additional paid-in capital as recorded against the gross proceeds.

Liquidity

The Company has incurred net losses and negative cash flows from operations since inception, has a significant accumulated deficit and expects to continue to incur net losses for the foreseeable future. The Company has never generated any revenue from product sales and does not expect to generate any revenues from product sales unless and until it successfully completes development of and obtains regulatory approval for its product candidates, which will not be for several years, if ever. The Company has an accumulated deficit of $246.7 million as of December 31, 2024. During the year ended December 31, 2024, the Company used $55.0 million of cash for operating activities. As of December 31, 2024, the Company has $185.4 million in cash, cash equivalents and investments. From inception through December 31, 2024, the Company has raised aggregate gross proceeds of $401.4 million to fund operations, comprised primarily from proceeds received from the IPO, including proceeds from the underwriters partial exercise of their purchase option, issuances of convertible promissory notes, simple agreements for future equity ("SAFEs") and private placements of convertible preferred stock. Since inception through December 31, 2024, the Company has also received $39.9 million in upfront and reimbursable research service payments from Merck Sharp & Dohme Corp. ("Merck"). The Company believes its existing cash, cash equivalents and investments will be sufficient to fund planned operations for at least one year from the issuance of these financial statements. As such, the prior substantial doubt about the Company's ability to continue as a going concern as discussed in the Company's December 31, 2023 audited financial statements as included in the Company's final prospectus dated July 18, 2024 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, no longer exists.

If the Company is unable to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, if ever, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue plans to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Accounting estimates and management judgments reflected in the financial statements include: revenue recognized, the accrual of research and development expenses, common stock, stock-based compensation, SAFEs and operating lease liabilities. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash, cash equivalents, and investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Segment Reporting

The Company's chief operating decision maker ("CODM") is the Chief Executive Officer. The Company has determined that it operates in one operating segment as it only reports operating results on an aggregate basis to the CODM. See Note 13 for segment financial information.

Determination of Fair Value of Certain Liability Instruments

The SAFEs are recorded as a liability in the balance sheets and the Company records subsequent changes in fair value in changes in fair value of SAFEs in the statements of operations and comprehensive loss. Debt issuance costs related to the SAFEs are expensed in the period incurred. Refer to Note 7 for further information on the SAFEs.

Allowance for Credit Losses

For investments in an unrealized loss position, the Company first assesses whether it intends to sell, or is more likely than not that it will be required to sell, the investment before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the investment's amortized cost basis is written down to fair value through earnings. For investments that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes in interest rates, and any changes to the rating of the security by a rating agency, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized

cost basis of the investment. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive loss.

Fair Value of Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 – Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Investments

The Company holds investments in commercial paper, government and government agency bonds, and corporate bonds. Short-term investments have initial maturities of greater than three months from date of purchase. The Company has classified its investment securities as current assets in the balance sheets because these are considered highly liquid securities and are available for use in current operations. All investments are accounted for as available-for-sale because these investment securities are considered available for use in operations. The Company carries these securities at fair value and reports unrealized gains and losses as a separate component of accumulated other comprehensive income. The cost of debt securities is adjusted for amortization of purchase premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income, net in the statements of operations and comprehensive loss. Realized gains and losses on sales of securities are determined using the specific identification method and recorded in other income, net in the statements of operations and comprehensive loss.

As of December 31, 2024 and 2023, accrued interest receivables on investments were $0.9 million and $0.1 million, respectively, and are included in prepaid expenses and other current assets in the Company's balance sheets. The Company does not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized cost basis of the investment. Uncollectible accrued interest receivables associated with an impaired debt security are reversed against interest income upon identification of the impairment. No accrued interest receivables were written off during the years ended December 31, 2024 and 2023.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available operating accounts, money market funds, and government bonds. The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents.

Restricted Cash

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash as of December 31, 2024 and 2023, was $0.3 million consisting of collateral for letters of credit related to the Company's lease agreements and is included in non-current assets in the balance sheets (see Note 11).

Property and Equipment, Net

Property and equipment, net is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally two to five years). The Company capitalizes laboratory equipment used for research and development if it has alternative future use in research and development or otherwise. Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Leasehold improvements are stated at cost and depreciated over the shorter of the estimated useful life or remaining lease term.

Impairment of Long-Lived Assets

The Company accounts for the impairment of long-lived assets by reviewing these assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group is not recoverable on an undiscounted-cash-flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. The Company did not recognize impairment losses for the years ended December 31, 2024 or 2023.

Research and Development Expenses and Accrued Research and Development Costs

Research and development expenses include costs to third-party contractors to perform research and development activities, internal related salaries, benefits, stock-based compensation charges for those individuals involved in research and development efforts, and associated overhead expenses. Research and development costs are expensed as incurred.

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants, and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects research and development expenses in its financial statements by matching those expenses with the period in which services and efforts are expended, as measured by the timing of various aspects of the preclinical or clinical study or related activities. The Company determines accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies, or other services being conducted. As of December 31, 2024, the Company has had no material differences between its estimates of such expenses and the amounts actually incurred. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed, or services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Licenses

Upfront payments and other consideration under license agreements are expensed as research and development expense upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred.

Certain license agreements include milestone payments which are recognized when it becomes probable that the achievement of certain milestones will be met. The Company records this expense as research and development expense in its statements of operations and comprehensive loss.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the statements of operations and comprehensive loss.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use ("ROU") asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows is substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term.

Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding ROU assets are recognized in the balance sheets at the commencement date of the lease based on the present value of lease payments over the expected lease term. Certain adjustments to the ROU asset may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to not separate between lease and non-lease components.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock option grants and restricted stock unit grants, estimated in accordance with the applicable accounting guidance, recognized on a straight-line basis over the vesting period. The vesting period generally approximates the expected service period of the awards. Additionally, the cost associated with the employee stock purchase plan is included within stock-based compensation expense. The Company recognizes forfeitures as they occur.

The fair value of stock options is estimated using a Black-Scholes valuation model on the date of grant. This method requires certain assumptions be used as inputs, such as the fair value of the underlying common stock, expected term of the option before exercise, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. Options granted have a maximum contractual term of 10 years. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development, as there is limited stock price data

available of the Company's common stock since the IPO. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options. The Company has historically not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore has estimated the dividend yield to be zero.

The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same way the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

Common Stock Valuation

Due to the absence of an active market for the Company's common stock prior to the IPO, the Company utilized methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: Valuation of Privately-Held Company Equity Securities Issued as Compensation to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the fair value of the common stock as of the grant date. The fair value of the common stock was determined based upon a variety of factors, including valuations the Company's common stock performed by independent third-party valuation specialists; the anticipated capital structure that will directly impact the value of the currently outstanding securities; the Company's results of operations and financial position; the status of the Company's research and development efforts; the composition of, and changes to, the Company's management team and board of directors; the lack of liquidity of the Company's common stock as a private company; the Company's stage of development and business strategy and the material risks related to the Company's business and industry; external market conditions affecting the life sciences and biotechnology industry sectors; U.S. and global economic conditions; the likelihood of achieving a liquidity event for the holders of the Company's common stock, such as an IPO or a sale of the Company, given prevailing market conditions; and the market value and volatility of comparable companies.

Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Collaboration, License, and Development Support Revenue

The Company recognizes revenue from its collaboration, license and development support agreements, in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. The Company applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract: (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices); (ii) each party's rights regarding the product or the service to be transferred can be identified; (iii) the payment terms for the product or service to be transferred can be identified; (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract); and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product

or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts; and (ii) the most likely amount method, which identifies the single most likely amount in a range of possible consideration amounts. The amount of variable consideration is included in the transaction price to the extent it is probable that a significant reversal of revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. The Company has not recorded any such liabilities as of December 31, 2024 or 2023.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2024 and 2023, the Company maintained full valuation allowances against its deferred tax assets as the Company concluded it had not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within the provision for income taxes in the statements of operations and comprehensive loss. Any accrued interest and penalties are included within the related tax liability in the balance sheets. As of December 31, 2024, the Company had no accrued interest or penalties.

Comprehensive Loss

Comprehensive loss consists of net loss in excess of unrealized gains and losses on investments. The Company displays comprehensive loss and its components as part of the statements of operations and comprehensive loss.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities include shares of its convertible preferred stock, as well as outstanding stock options and restricted stock units under the Company's equity incentive plan and have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive for the years ended December 31, 2024 and 2023:

	AS OF DECEMBER 31, 2024	AS OF DECEMBER 31, 2023
Convertible preferred stock	—	6,160,385
Unvested restricted stock units	529,359	22,514
Options to purchase common stock	2,216,215	1,315,726
SAFEs (1)	—	—
Total	2,745,574	7,498,625

(1) The contingently convertible SAFEs were not included for purposes of calculating the number of diluted shares outstanding as of December 31, 2023, as the number of dilutive shares was based on a conversion ratio associated with the pricing of a future financing or liquidation event. Therefore, the contingently convertible SAFEs' conversion ratio, and the resulting number of dilutive shares, was not determinable until the contingency was resolved. In connection with the closing of the IPO, the Company's outstanding convertible SAFE shares automatically converted into 2,391,418 shares of common stock.

Recently Adopted Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). ASU 2020-06 was issued to reduce the complexity associated with accounting for certain financial instruments with characteristics of liabilities and equity. ASU 2020-06 reduces the number of accounting models for convertible debt instruments and redeemable convertible preferred stock and improves the disclosures for convertible instruments and related

earnings per share guidance. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity and improves and amends the related earnings per share guidance. For public entities that qualify as a filer with the Securities and Exchange Commission, excluding entities eligible to be smaller reporting companies, ASU 2020-06 is effective for fiscal annual periods beginning after December 15, 2021, including interim periods within those fiscal years. For nonpublic entities, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. ASU 2020-06 must be adopted as of the beginning of a Company's annual fiscal year. The Company adopted this standard on January 1, 2024, and the adoption of the standard did not have a material impact on its financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The update requires entities to disclose their significant segment expense categories and amounts for each reportable segment. Significance is assessed using both quantitative and qualitative factors depending on the facts and circumstances. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. The Company adopted this standard for the fiscal year 2024 annual financial statements and interim financial statements thereafter and has applied this standard retrospectively for all prior periods presented in the financial statements. See Note 13 – Segment Reporting for further information.

Recently Issued Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures* ("ASU 2023-09"). The update requires enhanced disclosures on income taxes paid, adds disaggregation of continuing operations before income taxes between foreign and domestic earnings and defines specific categories for the reconciliation of jurisdictional tax rate to effective tax rate. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, and can be applied on a prospective basis. The Company is currently evaluating the impact that this standard will have on the related disclosures in its financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The standard requires that public business entities disclose additional information about specific expense categories in the notes to financial statements for interim and annual reporting periods. The guidance is effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. The guidance is applied on a prospective basis, with a retrospective option, and early adoption is permitted. We are currently evaluating the impact of adoption of this standard on our financial statements and disclosures.

3. Fair Value Measurements

The following table presents information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicates their respective levels within the fair value hierarchy (in thousands):

		AS OF DECEMBER 31, 2024			
	CLASSIFICATION	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
Assets					
Money market funds	Cash and cash equivalents	$ 31,553	$ 31,553	$ —	$ —
Government bonds	Cash and cash equivalents	6,574	—	6,574	—
Commercial paper	Short-term investments	64,855	—	64,855	—
Government and government agency bonds	Short-term investments	59,458	—	59,458	—
Corporate bonds	Short-term investments	20,880	—	20,880	—
Total assets		$ 183,320	$ 31,553	$ 151,767	$ —

	CLASSIFICATION	AS OF DECEMBER 31, 2023 TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
Assets					
Money market funds	Cash and cash equivalents	$ 28,517	$ 28,517	$ —	$ —
Commercial paper	Short-term investments	2,090	—	2,090	—
Government and government agency bonds	Short-term investments	19,982	—	19,982	—
Corporate bonds	Short-term investments	1,395	—	1,395	—
Total assets		$ 51,984	$ 28,517	$ 23,467	$ —
Liabilities					
SAFEs	Liabilities	$ 25,100	$ —	$ —	$ 25,100
Total liabilities		$ 25,100	$ —	$ —	$ 25,100

The carrying amounts of all cash and cash equivalents, accounts receivable, other receivables, prepaid and other current assets, accounts payable, and accrued expenses are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Short-Term Investments

The Company's assets with a fair value categorized as Level 2 within the fair value hierarchy consist of commercial paper, government and government agency bonds, and corporate bonds. These assets have been initially valued at the transaction price and subsequently valued at the end of each reporting period utilizing third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable.

Simple Agreements for Future Equity

The estimated fair value of the SAFEs (see Note 7) is determined based on the aggregated, probability-weighted average of the outcomes of certain scenarios, including: (i) equity financing, with conversion of the SAFEs into a number of shares of convertible preferred stock at the lower of the post-money valuation cap price of $48.25 and the discount price (the lowest price of the standard convertible preferred stock sold in the equity financing multiplied by the specified discount rate of 85%); (ii) liquidity event (change of control, direct listing, or an initial public offering,) with mandatory conversion to common stock at the lower of post-money valuation cap price of $48.25 and discount price (price of the common stock multiplied by the discount rate of 85%); and (iii) dissolution event, with SAFE holders automatically entitled to receive cash payments equal to the purchase amount, prior to and in preference to any distribution of any assets or surplus funds to the holders of convertible preferred and common stock. On May 29, 2024, the Company executed an amendment to the SAFEs (the "SAFE Amendment"). The SAFE Amendment amended the definition of liquidity event to exclude an initial public offering and amended the definition of the discount price under an initial public offering to the lower of (a) the price per share of common stock sold to the public by the underwriters in the initial public offering multiplied by the discount rate of 85% or (b) the post-money valuation cap price of $48.25. The combined value of the probability-weighted average of those outcomes is then discounted back to each reporting period in which the SAFEs are outstanding, in each case based on a risk-adjusted discount rate estimated based on the implied interest rate using the changes in observed interest rates of corporate debt that the Company believes is appropriate for those probability-adjusted cash flows.

Fair value measurements associated with SAFEs were determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. Increases and decreases in the fair value of the SAFEs can result from updates to assumptions such as expected timing and probability of a qualified financing event, or changes in discount rates, among other assumptions. Based on management's assessment of the valuation of the SAFEs, performed by the Company's third-party valuation specialists, none of the changes in the fair value of those instruments were due to changes in the Company's own credit risk for the reporting periods presented. Judgment is used in determining these assumptions as of the initial valuation date and at

each subsequent reporting period. Changes or updates to assumptions could have a material impact on the reported fair value, and the change in fair value of SAFEs and the results of operations in any given period.

In connection with the closing of the IPO, the Company's outstanding convertible SAFE shares automatically converted into 2,391,418 shares of common stock.

The following tables summarize the significant inputs not observable in the market upon which the fair value measurements associated with the SAFEs were determined:

	VALUATION TECHNIQUE	UNOBSERVABLE INPUT	AS OF DECEMBER 31, 2023
Liabilities			
SAFEs	Scenario-based approach	Probability weighting	15.0% - 70.0%
		Discount rate	20.1%
		Remaining term to event (in years)	0.50 - 0.75

The following table summarizes the changes in fair value associated with Level 3 financial instruments held during the year ended December 31, 2024 (in thousands):

	SAFEs
Balance at December 31, 2023	$ 25,100
Changes in fair value of SAFEs	3,597
Conversion of SAFEs to common stock	(28,697)
Balance at December 31, 2024	$ —

4. Cash, Cash Equivalents and Short-Term Investments

It is the Company's policy to mitigate credit risk in its financial assets by maintaining a well-diversified portfolio that limits the amount of exposure as to maturity and investment type.

The following table summarizes the Company's cash, cash equivalents and short-term investments (in thousands):

			AS OF DECEMBER 31, 2024			
	CLASSIFICATION	MATURITY	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR MARKET VALUE
Cash and money market funds	Cash and cash equivalents	Less than three months	$ 33,661	$ —	$ —	$ 33,661
Government bonds	Cash and cash equivalents	Less than three months	6,572	2	—	6,574
Commercial paper	Short-term investments	1 year or less	64,840	30	(15)	64,855
Government and government agency bonds	Short-term investments	1 year or less	17,422	7	(1)	17,428
Corporate bonds	Short-term investments	1 year or less	15,539	—	(9)	15,530
Government and government agency bonds	Short-term investments	Greater than 1 year	42,157	1	(128)	42,030
Corporate bonds	Short-term investments	Greater than 1 year	5,366	9	(25)	5,350
Total cash, cash equivalents and short-term investments			$ 185,557	$ 49	$ (178)	$ 185,428

			AS OF DECEMBER 31, 2023			
	CLASSIFICATION	MATURITY	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR MARKET VALUE
Cash and money market funds	Cash and cash equivalents	Less than three months	$ 53,504	$ —	$ —	$ 53,504
Commercial paper	Short-term investments	1 year or less	2,048	42	—	2,090
Government and government agency bonds	Short-term investments	1 year or less	19,728	254	—	19,982
Corporate bonds	Short-term investments	1 year or less	1,383	12	—	1,395
Total cash, cash equivalents and short-term investments			$ 76,663	$ 308	$ —	$ 76,971

At December 31, 2024, the Company had 12 securities with contractual maturities of one year or less and 21 securities with contractual maturities greater than one year in an unrealized loss position, all of which have been in an unrealized loss position for less than 12 months. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis. As of December 31, 2024, no allowance for credit losses was recorded.

5. Property and Equipment, Net

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

	AS OF DECEMBER 31, 2024	DECEMBER 31, 2023
Lab equipment	$ 10,395	$ 9,760
Furniture and fixtures	871	871
Computers and software	617	607
Leasehold improvements	410	390
	12,293	11,628
Less accumulated depreciation	(5,923)	(3,532)
Total property and equipment, net	$ 6,370	$ 8,096

The Company recognized $2.4 million and $2.3 million in depreciation expense for the years ended December 31, 2024 and 2023, respectively.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	AS OF DECEMBER 31, 2024	DECEMBER 31, 2023
Accrued research and development expenses	$ 1,472	$ 2,861
Accrued payroll and other employee benefits	4,831	4,047
Other accrued expenses	1,089	1,109
Total accrued expenses	$ 7,392	$ 8,017

7. Simple Agreement for Future Equity

During 2023, the Company entered into SAFEs with various existing investors and related parties with aggregate gross proceeds of $24.4 million. The SAFEs granted investors with rights to participate in a future equity financing. The SAFEs have no maturity dates and bear no interest. Upon an equity financing, the SAFEs will automatically convert into the type of stock issued in the financing at a per share conversion price equal to the greater of (i) the purchase amount of the SAFEs divided by the post-money valuation cap price of $48.25 per share, or (ii) the purchase amount of the SAFEs divided by the 85% per share price paid by investors in the financing. Upon an initial public offering, the SAFEs will automatically convert into shares of common stock equal to the purchase amount of the SAFE divided by the discount price (the lower of (a) the price per share of common stock sold to the public by the underwriters in the initial public offering multiplied by the discount rate of 85% or (b) the post-money valuation cap price of $48.25 per share). Other conversion events include liquidity events (a change of control or direct listing). Upon a liquidity event, each investor will automatically be entitled to receive a portion of proceeds equal to the greater of (i) the purchase amounts of the SAFEs, or (ii) the amount payable in the number of common shares equal to the purchase amount of the SAFEs divided by the 85% per share price. Upon a dissolution event and to the extent sufficient funds are available, the holders of SAFEs shall be entitled to receive cash payments equal to the purchase amount, prior to and in preference to any distribution of any assets or surplus funds to the holders of convertible preferred and common stock.

In connection with the closing of the IPO, the Company's outstanding convertible SAFE shares automatically converted into 2,391,418 shares of common stock.

8. Collaboration and License Agreements

The Company has entered into several agreements with GC Cell and related entities concerning its NK cell therapy platform and manufacturing of its core products, as described below.

Option and License Agreement with GC Cell

In September 2019, the Company entered into an option and license agreement with GC Cell Corporation ("GC Cell"), formerly Green Cross Cell Corporation, as amended in June 2020 and February 2022 (the "Core Agreement"). Under the Core Agreement, GC Cell granted the Company an exclusive, royalty-bearing license, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell relating to non-genetically modified and genetically modified NK cells, and culturing, engineering, manufacturing thereof, to research, develop, manufacture, and commercialize NK cell pharmaceutical products in the Artiva Territory, which is anywhere in the world except for Asia, Australia, and New Zealand. GC Cell retained rights under the license to allow it and its affiliates to perform obligations under the Core Agreement and other agreements between the Company and them.

Under the Core Agreement, GC Cell agreed to conduct a discovery, research, preclinical development, and manufacturing program under a plan approved by a Joint Steering Committee (the "JSC"), to generate and identify product candidates for nomination as option candidates. GC Cell will bear all costs for its work under the R&D Plan, except that the Company will bear all costs for completing IND-enabling activities performed by GC Cell on behalf of the Company, other than certain efficacy studies.

For each product candidate determined by the JSC to be an option candidate, the Company has an exclusive option under the Core Agreement to obtain an exclusive, sublicensable license to research, develop, manufacture and commercialize such candidate in the Artiva Territory for any therapeutic, prophylactic or diagnostic uses in humans, on economic terms to be determined in good faith by the parties. GC Cell retains exclusive rights to the licensed technology in Asia, Australia, and New Zealand, though the Company has the right to request, and GC Cell has agreed to consider in good faith, inclusion of Australia, New Zealand, and/or specific countries in Asia in the Artiva Territory on a product-by-product basis. If the Company elects not to exercise the option with respect to a particular option candidate, GC Cell retains the right to continue development of such candidate. As of December 31, 2024, the Company has exercised its rights to license four option candidates, AB-101 (AlloNK), AB-201, AB-202, and AB-205, as described below.

The Company has control over and will bear the costs of the development, regulatory, manufacturing, and commercialization activities relating to the option candidates for which it has exercised its option, each a licensed product. Accordingly, the Company has certain diligence obligations and must use commercially reasonable efforts to develop and seek regulatory approval for each licensed product in at least one indication in the United States and the European Union, and following regulatory approval in a country, to commercialize such licensed product in at least one indication in such country. The Core Agreement provides that the Company has the right to engage GC Cell or its appropriate affiliate to provide research and manufacturing services for the licensed products being developed by the Company in the Artiva Territory under separately executed service agreements.

Under the Core Agreement, the Company is obligated to pay a low single-digit percentage royalty on net sales of any licensed products, the manufacture, use or sale of which is claimed by or uses any Core IP. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company also has the exclusive option to extend its license to the Core IP to be worldwide with respect to products originated from the Company in exchange for a specified increase in the applicable royalty. GC Cell is also obligated to pay the Company a royalty at a rate equal to 50% of the royalty payable by the Company for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property. As of December 31, 2024, the Company has not recognized any net sales royalties under the Core Agreement.

AB-101 Selected Product License Agreement

In November 2019, the Company entered into a license agreement with GC Cell for its AB-101 product candidate, as amended in February 2022 (the "AB-101 Agreement"). AB-101 is the first product for which the Company exercised its option under the Core Agreement. Under the AB-101 Agreement, GC Cell granted the Company an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture, and commercialize AB-101.

Under the AB-101 Agreement, the Company is obligated to pay tiered royalties in the low-mid to high single-digit percentage range on annual net sales of any licensed AB-101 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-101 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company is also obligated to make milestone payments to GC Cell of: (1) up to $22.0 million upon the first achievement of certain development milestones; and (2) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay the Company a royalty at a rate equal to 50% of the royalty payable by the Company for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-101 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property. As of December 31, 2024, the Company has not recognized any net sales royalties or milestones under the AB-101 Agreement.

AB-201 Selected Product License Agreement

In October 2020, the Company entered into a license agreement with GC Cell for its AB-201 product candidate, as amended in February 2022 (the "AB-201 Agreement"). AB-201 is the second product for which the Company exercised its option under the Core Agreement. Under the AB-201 Agreement, GC Cell granted the Company an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture, and commercialize AB-201.

Under the AB-201 Agreement, the Company is obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-201 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-201 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company is also obligated to make milestone payments to GC Cell of: (1) up to $25.0 million upon the first achievement of certain development milestones; and (2) up to $55.0 million upon the first achievement of certain sales milestones. GC Cell is also obligated to pay the Company a royalty at a rate equal to 50% of the royalty payable by the Company for such product in the Artiva Territory on net sales outside the Artiva Territory of any licensed AB-201 product, the manufacture, use or sale of which is claimed by or uses any jointly owned intellectual property.

In September 2023, the Company entered into an amendment to the AB-201 Agreement (the "Amended AB-201 Agreement"). This amendment granted back to GC Cell an exclusive, royalty and milestone bearing license to all information and patents controlled by the Company that relate specifically to the research, development, manufacture and use of AB-201, to be used outside of the Artiva Territory. Under the Amended AB-201 Agreement, the Company will receive tiered royalties in the low single-digit percentage range on annual GC Cell net sales of AB-201 outside of the Artiva Territory. The royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of AB-201 outside of the Artiva Territory and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. The Company will also receive milestone payments upon achievement of certain development milestones, totaling $1.8 million. In December 2023, GC Cell achieved the first regulatory milestone under the Amended AB-201 Agreement for first IND acceptance for AB-201 outside the Artiva Territory.

The Company recognized $0.3 million and $0.6 million of license and development support-related revenue during the years ended December 31, 2024 and 2023, respectively, in the statements of operations and comprehensive loss, related to development support activities under the Amended AB-201 Agreement. As of December 31, 2024 and December 31, 2023, total accounts receivable related to the Amended AB-201 Agreement were zero and $0.6 million, respectively.

AB-205 Selected Product License Agreement

In December 2022, the Company entered into a license agreement with GC Cell for its AB-205 product candidate (the "AB-205 Agreement"). AB-205 is the fourth product for which the Company exercised its option under the Core Agreement. Under the AB-205 Agreement, GC Cell granted the Company an exclusive, royalty-bearing license in the Artiva Territory, with the right to sublicense through multiple tiers, under certain intellectual property and technology owned or controlled by GC Cell, to research, develop, manufacture, and commercialize AB-205.

Under the AB-205 Agreement, the Company is also obligated to pay tiered royalties in the mid to high single-digit percentage range on annual net sales of any licensed AB-205 products. The royalty rate is subject to reduction under certain scenarios, and royalties are payable on a product-by-product and country-by-country basis, beginning with the first commercial sale of a licensed AB-205 product and continuing until the later of: (i) expiration of the last-to-expire claim of the licensed patents and jointly owned patents in the country of sale; (ii) expiration of any regulatory exclusivity for a licensed product in that country; and (iii) the tenth anniversary of the first commercial sale of a licensed product in that country. Upon election by the Company to proceed with clinical development of AB-205 (prior to which the Company may not make, use or sell AB-205 for clinical development purposes), the Company is obligated to pay a one-time payment of $2.5 million to GC Cell. Thereafter, the Company is also obligated to make milestone payments to GC Cell of: (i) up to $29.5 million upon the first achievement of certain development milestones, excluding any payments for the Development Cost Share as defined in the AB-205 Agreement; and (ii) up to $28.0 million upon the first achievement of certain sales milestones. As of December 31, 2024, the Company has not recognized any net sales royalties or milestones under the AB-205 Agreement.

In connection with the AB-205 License Agreement, the Company recognized $0.1 million and $1.6 million of expense reimbursements for development costs invoiced to GC Cell for the years ended December 31, 2024 and 2023, respectively. During the years ended December 31, 2024 and 2023, the Company received payments from GC Cell totaling $0.7 million and $1.0 million, respectively. As of December 31, 2024 and December 31, 2023, the Company recorded zero and $0.6 million, respectively, in the balance sheets as other receivables from GC Cell.

Research Services Agreement with GC Cell

As contemplated by the Core Agreement, in August 2020 the Company entered into the GC Cell Research Services Agreement, as amended in February 2022, under which GC Cell agreed to provide research services in support of the research and development of one or more of the products the Company has licensed from GC Cell.

The agreement provides that the parties will agree to specific projects as work orders under the GC Cell Research Services Agreement. Each work order shall set forth, upon terms mutually agreeable to GC Cell and the Company, the specific services to be performed by GC Cell, the timeline and schedule for the performance of the services, and the compensation to be paid by the Company to GC Cell for the provision of such services, as well as any other relevant terms and conditions (see Note 10).

Master Manufacturing Agreement with GC Cell

In March 2020, the Company entered into a Master Agreement for Manufacturing Services (the "Manufacturing Agreement") with GC Cell, under which GC Cell agreed to manufacture specified products under individual work orders for use in the Company's Phase 1 and Phase 2 clinical trials. Each work order will contain an estimated budget of service fees and out-of-pocket costs to be incurred in the performance of services under the agreement and the work order, as well as additional terms and conditions relating to the estimated budget. The Company will own all results and data generated by GC Cell under the Manufacturing Agreement (see Note 10).

Merck Exclusive License and Collaboration Agreement

In January 2021, the Company entered into the Exclusive License and Research Collaboration Agreement (the "Merck Collaboration Agreement") with Merck for the discovery, development, manufacture and commercialization of CAR-NK cells that target certain solid tumor antigens. Merck paid the Company $30.0 million upfront for two target programs under the Merck Collaboration Agreement. As part of the Merck Collaboration Agreement, the Company was also eligible to receive additional payments for achieving certain development, regulatory approval and sales milestones, as well as royalties on net sales. In addition, the Company would be reimbursed for the conduct of each research program, including external research costs and manufacture and supply of clinical material for Phase 1 clinical trials.

Concurrent with entering into the Merck Collaboration Agreement, the Company also entered into an agreement with GC Cell to obtain exclusive, worldwide rights to GC Cell's CAR-NK technology with respect to the licensed products and to engage GC Cell to perform services in support of the research programs ("Partnered Program License Agreement"). The Company agreed to reimburse GC Cell for research and development services as these services were provided. The Company was required to pay GC Cell 100% of regulatory milestones, sales milestones and royalty payments received by Merck relating to products in Asia, Australia and New Zealand and 50% of upfront payments, license fees, regulatory milestones, sales milestones and royalty payments received by Merck relating to products in all other territories.

In October 2023, the Merck Collaboration Agreement and development thereunder was terminated by Merck.

The Company applied ASC 808 to the Merck Collaboration Agreement and determined that the agreements were applicable to such guidance. The Company concluded that Merck represented a customer and applied relevant guidance from ASC 606 to account for the Merck Collaboration Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of a license to Merck to certain of its intellectual property subject to certain conditions, transfer of technology, its conduct of research services, and its participation in a joint research committee. The Company determined that its grant of a license to Merck to certain of its intellectual

property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research services.

Additionally, the Company determined that its conduct of research services was not distinct from other performance obligations since the research could not be conducted without also delivering the rights to the license, developed intellectual property and technology transfer. Accordingly, the Company determined that all performance obligations should be accounted for as one combined performance obligation for each target program, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is collectively estimated to be four years, which represents the combined terms for the research programs ("Expected Research Term").

The Company assessed the upfront, non-refundable and non-creditable payment of $30.0 million received in January 2021 and concluded that there was not a significant financing component to the Merck Collaboration Agreement.

The Company also assessed the effects of the variable consideration under the Merck Collaboration Agreement. Such assessment evaluated, among other things, the likelihood of receiving: (i) various clinical, regulatory and commercial milestone payments; and (ii) royalties on net sales. Based on its assessment, the Company concluded that given the substantial uncertainty related to their achievement, such variable consideration was not included in the transaction price.

In accordance with ASC 606, the Company determined that the initial transaction price under the Merck Collaboration Agreement equaled $58.0 million, consisting of the upfront, non-refundable and non-creditable payment of $30.0 million and the aggregate estimated research and development fees of $28.0 million. The initial transaction price was allocated evenly to each of the two product targets. The upfront payment of $30.0 million was recorded as deferred revenue, and was recognized as revenue over the Expected Research Term as the research services were the primary component of the combined performance obligations. Revenue associated with the upfront payment was recognized based on actual costs incurred as a percentage of the estimated total costs expected to be incurred over the Expected Research.

The Company assessed the payments made to GC Cell in connection with the Partnered Program License Agreement and concluded that all payments received from Merck and paid to GC Cell should be reflected within the Company's financial statements on a gross basis. The Company recognized payments from Merck as collaboration revenue as the performance obligation was satisfied over time, and payments made to GC Cell were recognized as research and development expense, as incurred.

The Company recognized zero and $32.9 million of revenue under the Merck Collaboration Agreement during the years ended December 31, 2024 and 2023, respectively. Over the course of the Merck Collaboration Agreement through December 31, 2024, the Company received $39.9 million in payments from Merck, of which $30.0 million related to the upfront fee, and $9.9 million related to reimbursable research services.

Affimed Collaboration Agreement

On November 1, 2022, the Company entered into a strategic collaboration agreement with Affimed GmbH, a subsidiary of Affimed N.V. ("Affimed") for the clinical development and commercialization of a combination therapy, for any uses in humans or animals, comprising Affimed's product consisting of an innate cell engager referred to as "AFM13" and the Company's product containing an NK cell referred to as AB-101 (the "Affimed Collaboration Agreement"). While the collaboration is initially limited to the United States, the parties will, upon Affimed's request, in good faith discuss an expansion to certain other territories.

The Company has granted Affimed, with respect to the development of the combination therapy an exclusive, and with respect to the promotion of the combination therapy under the Affimed Collaboration Agreement a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free and non-sublicensable (with certain exceptions) license under relevant Company patents and know-how. Affimed has granted the Company a non-exclusive, non-transferable (except to affiliates and successors in interest), royalty-free license and

non-sublicensable (with certain exceptions) license under relevant Affimed patents and know-how for use in the clinical development of the combination therapy under the Affimed Collaboration Agreement.

The financial terms of the Affimed Collaboration Agreement provides that Affimed shall be responsible for all costs associated with the development of the combination therapy (including all clinical trial costs), except that Affimed and the Company shall each bear 50% of the costs and expenses incurred in connection with the performance of any confirmatory combination therapy clinical trial required by the FDA. The Company shall be solely responsible for all costs incurred by the Company for the supply of AB-101 and IL-2 product used in the clinical trials for the combination therapy, and for carrying out activities assigned to it under the agreed development plan. In addition, under the Affimed Collaboration Agreement, the parties agree to make payments to each other to achieve a proportion of 67%/33% (Affimed/Company) of revenues generated by both parties from commercial sales of each party's product as part of the combination therapy.

During the years ended December 31, 2024 and 2023, the Company incurred $0.1 million and $0.9 million in expenses in connection with the Affimed Collaboration Agreement, respectively.

9. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Stockholders' Equity (Deficit)

Under the Amended and Restated Certificate of Incorporation dated July 22, 2024, the Company had a total of 710,000,000 shares of capital stock authorized for issuance, consisting of 700,000,000 shares of common stock, par value of $0.0001 per share, and 10,000,000 shares of preferred stock, par value of $0.0001 per share. Additionally, the Company has authorized 84,556 shares reserved under the terms specified as part of the Company's Pledge 1% Movement commitment, in support of its corporate social responsibility and philanthropic pursuits.

Convertible Preferred Stock

In 2020 and 2021, the Company issued 2,077,165 shares and 1,595,983 shares, respectively, of Series A convertible preferred stock at a price of $21.93 per share, resulting in aggregate gross proceeds of $70.0 million and total issuance costs of $0.4 million. The Company converted a promissory note with a fair value of $10.6 million as part of the first closing and reclassified a convertible preferred stock purchase right liability with a fair value of $23.7 million into equity as part of the second closing.

In 2021, the Company issued 2,487,237 shares of Series B convertible preferred stock at a price of $48.25 per share resulting in aggregate gross proceeds of $120.0 million and incurred $0.4 million of total issuance costs.

As of December 31, 2023, the Company's Series A and Series B convertible preferred stock was classified as temporary equity in the balance sheets given that the holders of the convertible preferred stock could cause certain events to occur that are outside of the Company's control whereby the Company could be obligated to redeem the convertible preferred stock. The carrying value of the convertible preferred stock was not adjusted to the redemption value until the contingent redemption events are considered to be probable of occurring.

The Company's convertible preferred stock had the following rights, preferences and privileges:

Dividends

The Company shall not declare, pay or set aside any dividends on shares of any class of capital stock of the Company unless the holders of the Series A or Series B convertible preferred stock shall first receive, or simultaneously receive, a dividend on each outstanding share of the Series A convertible preferred stock equal to an amount as defined in the Company's Amended and Restated Certificate of Incorporation. No such dividends have been declared or paid through December 31, 2024.

Preferences on Liquidation

The holders of the Series A convertible preferred stock are entitled to receive liquidation preferences, in the event of a change in control, at an amount per share equal to the greater of (i) the Series A original issuance price of $21.93, plus any dividends declared but unpaid or (ii) such amount per share as would have been payable had all shares of Series A convertible preferred stock been converted into common stock. The holders of the Series B convertible preferred stock are entitled to receive liquidation preferences, in the event of a change in control, at an amount per share equal to the greater of (1) the Series B original issuance price of $48.25, plus any dividends declared but unpaid or (2) such amount per share as would have been payable had all shares of Series B convertible preferred stock been converted into common stock. Liquidation payments to the holders of the Series A and Series B convertible preferred stock have priority and are made in preference to any payments to the holders of common stock.

After full payment of the liquidation preference to the holders of the Series A and Series B convertible preferred stock, the remaining assets, if any, will be distributed ratably to the holders of the common stock.

Conversion Rights

The shares of Series A and Series B convertible preferred stock are convertible into an equal number of shares of common stock, at the option of the holder, subject to certain anti-dilution adjustments. The conversion rate for the convertible preferred stock is determined by dividing the original issue price by the conversion price. The conversion price is initially the original issue price, but is subject to adjustment for dividends, stock splits, and other distributions. The conversion rate at December 31, 2023, for the Series A and Series B convertible preferred stock was 1:1.

Each share of Series A convertible preferred stock will be automatically converted into common stock at the then effective conversion rate (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock) upon: (i) the closing of the sale of common stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75.0 million of gross proceeds to the Company; or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of 60% of the outstanding shares of Series A convertible preferred stock. Each share of Series B convertible preferred stock will be automatically converted into common stock at the then effective conversion rate (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock) upon: (1) the closing of the sale of common stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement Securities Act of 1933, as amended, resulting in at least $75.0 million of gross proceeds to the Company; or (2) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of 60% of the outstanding shares of Series B convertible preferred stock.

Redemption Rights

The holders of Series A and Series B convertible preferred stock do not have any redemption rights, except upon certain liquidation events that are outside of the Company's control.

Voting

The holder of each share of Series A and Series B convertible preferred stock generally vote together with the shares of common stock as a single class, but also have class vote approval rights as provided by the Company's certificate of incorporation or as required by applicable law.

Immediately upon completion of the IPO, 6,160,385 outstanding shares of convertible preferred stock converted into 6,160,385 shares of common stock. There are no Series A or Series B convertible preferred shares outstanding as December 31, 2024.

Common Stock

The voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the Series A and Series B convertible preferred stock. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

	AS OF	
	DECEMBER 31, 2024	DECEMBER 31, 2023
Convertible preferred stock	—	6,160,385
Common stock options granted and outstanding	2,216,215	1,315,726
Restricted stock units granted and outstanding	529,359	22,514
Shares available for issuance under the 2024 and 2020 equity incentive plans, respectively	1,820,868	323,131
Shares available for issuance under the ESPP Plan	212,000	—
Shares available for issuance under the Pledge 1% commitment	84,556	84,556
Total common stock reserved for future issuance	4,862,998	7,906,312

Stock Options

In June 2020, the Company adopted the 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan provides for the grant of incentive stock options ("ISO"), non-statutory stock options ("NSO"), stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards.

The 2020 Plan was amended in December 2020, January 2021, July 2021, August 2022, and in April 2024. In April 2024, the 2020 Plan was amended to increase the total number of shares reserved under the 2020 Plan to 2,083,797.

In July 2024, in connection with the closing of the IPO, the Company's board of directors adopted the 2024 Equity Incentive Plan (the "2024 Plan"), a successor to and continuation of the 2020 Plan. Upon the effectiveness of the 2024 Plan, 4,572,025 shares of common stock were authorized for issuance which consists of (1) 2,630,000 new shares of common stock, (2) 115,436 shares available for issuance under the 2020 Plan, and (3) up to 1,826,589 shares of common stock subject to outstanding stock awards granted under the 2020 Plan that, on or after the 2024 Plan becomes effective, expire or otherwise terminate prior to exercise or settlement; are not issued because the stock award is settled in cash; are forfeited or repurchased because of the failure to vest; or are reacquired or withheld to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. Furthermore, upon effectiveness of the 2024 Plan, no further grants will be made under the 2020 Plan, and the 2020 Plan will automatically terminate on June 23, 2030.

Options granted under the 2024 Plan are exercisable at various dates as determined upon grant and will expire no more than 10 years from their date of grant. The exercise price of each option shall be determined by the board of directors based on the estimated fair value of the Company's stock on the date of the option grant. The exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. Most option grants generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years and early exercise is permitted. The vesting period generally occurs over four years unless there is a specific performance vesting trigger at which time those shares will vest when the performance trigger is probable to occur.

On April 6, 2023, the Company's board of directors approved a stock option repricing (the "Option Repricing") in which the exercise price of certain outstanding options to purchase shares of the Company's common stock under the 2020 Plan was reduced to $5.00 per share, the estimated fair value of the Company's common stock as of December 31, 2022. The Option Repricing was intended to motivate holders of options with exercise prices in excess of the estimated fair value of the Company's common stock to remain with the Company and work toward its success. The Option Repricing included options granted pursuant to the 2020 Plan that were held by, among others, members of the Company's board of directors and the Company's named executive officers.

As a result of the Option Repricing, 1,168,651 shares of vested and unvested stock options outstanding as of April 6, 2023, with original exercise prices ranging from $5.14 to $51.72 per share, were repriced to an exercise price of $5.00 per share. The Option Repricing impacted 70 grantees and the total incremental fair value recognized as a result of the repricing was $1.5 million. During the years ended December 31, 2024 and 2023, the Company recorded $0.4 million and $0.8 million of stock-based compensation expense in relation to the Option Repricing, respectively.

A summary of the Company's stock option activity under the 2020 Plan and 2024 Plan is as follows:

	TOTAL OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (in years)	AGGREGATE INTRINSIC VALUE (in thousands)
Outstanding at December 31, 2023	1,315,726	$ 5.02	9.1	$ 214
Granted	1,064,839	11.17	—	—
Exercised	(10,046)	5.04	—	—
Cancelled	(154,304)	8.59	—	—
Outstanding at December 31, 2024	2,216,215	$ 7.72	8.7	$ 7,118
Exercisable as of December 31, 2024	1,135,571	$ 5.08	8.1	$ 5,686

For the year ended December 31, 2024, the Company recorded $6.2 million in stock-based compensation related to employee and non-employee options. The weighted-average grant date fair value of options granted for the years ended December 31, 2024 and 2023, was $8.79 and $3.27 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2024 and 2023, was de minimus. Upon the exercise of stock options, the Company will issue new shares of its common stock. As of December 31, 2024, the unrecognized compensation cost related to outstanding employee and non-employee options was $10.4 million and is expected to be recognized as expense over a weighted-average period of 2.8 years.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and non-employee stock option grants issued for the years ended December 31, 2024 and 2023, were as follows:

	YEAR ENDED DECEMBER 31,	
	2024	2023
Stock price	$5.18 - $15.45	$ 5.00
Risk-free rate of interest	3.5% - 4.6%	3.6% - 4.4%
Expected term (years)	5.1 - 6.1	5.5 - 6.1
Expected stock price volatility	87.2% - 110.5%	86.5% - 88.6%
Expected dividend yield	—	—

Employee Stock Purchase Plan

In connection with the closing of the IPO, the Company's board of directors adopted the 2024 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for two-year offering periods consisting of four 6-month purchase periods, and at the end of each purchase period employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last trading day of the purchase period. A new offering is initiated each January 16 and July 16. In the event the fair market value of the Company's common stock on the first day of any new offering is less than or equal to the fair

market value of a ongoing offering, the ongoing offering shall terminate immediately following the purchase of shares of common stock on the purchase date immediately preceding the new offering and participants in the terminated ongoing offering will be automatically enrolled in the new offering.

An aggregate of 212,000 shares were initially reserved and available for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2025, by the lesser of 1.0% of the outstanding number of shares of common stock on the immediately preceding December 31, and 424,000 shares of common stock. No shares were issued under the ESPP as of December 31, 2024.

The ESPP is considered a compensatory plan, and for the year ended December 31, 2024 the Company recorded related stock-based compensation of $0.2 million. The assumptions used to estimate the fair value of ESPP awards using the Black-Scholes option valuation model were as follows:

	YEAR ENDED DECEMBER 31, 2024
Stock price	$ 11.91
Risk-free rate of interest	4.4% - 5.2%
Expected term (years)	0.5 - 2.0
Expected stock price volatility	84.4% - 87.9%
Expected dividend yield	—

Restricted Stock Unit Awards

Restricted stock unit awards ("RSUs") granted under the 2020 and 2024 Plan are subject to time-based vesting and convert to shares of common stock in accordance with the vesting schedule. RSUs are valued at the estimated fair value of the Company's stock on the date of grant and are amortized over the requisite service period. The total number of RSUs granted represents the maximum number of RSUs eligible to vest based upon the service conditions set forth in the grant agreements. Employees forfeit unvested RSUs upon termination of employment with a corresponding reversal of expense.

During the years ended December 31, 2024 and 2023, 534,095 and zero RSUs were granted by the Company, respectively. As of December 31, 2024, 529,359 total RSUs were outstanding.

The following table summarizes RSU activity under the 2020 and 2024 Plan during the year ended December 31, 2024:

	NUMBER OF STOCK UNITS	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested balance at January 1, 2024	22,514	$ 46.83
Granted	534,095	11.43
Vested	(22,514)	46.83
Forfeited	(27,250)	14.20
Unvested balance at December 31, 2024	506,845	$ 11.28

For the year ended December 31, 2024, the Company recorded $0.5 million in stock-based compensation related to RSUs. As of December 31, 2024, the unrecognized compensation cost related to outstanding RSUs was $5.2 million and is expected to be recognized as expense over a weighted-average period of 3.6 years. The total fair value of RSUs vested during the year ended December 31, 2024 was approximately $1.1 million.

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense by financial statement line item in the Company's statements of operations and comprehensive loss (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Research and development	$ 3,414	$ 3,639
General and administrative	3,566	3,414
Total	$ 6,980	$ 7,053

In 2023, the Company entered into separation agreements with certain executives, terminating their employment and entering into consulting agreements. Under the separation agreements, service-based requirements for one of the executives were deemed satisfied for all RSUs as of the date of separation. In order for RSUs to vest, there must be a liquidity event and the RSUs must meet the time and service-based requirement prior to the defined Liquidity Event Deadline. There were no outstanding RSUs associated with these executives as of December 31, 2024. The Company recognized zero in incremental compensation cost for the year ended December 31, 2024, and $0.5 million in incremental compensation cost for the year ended December 31, 2023 in relation to the service-based requirement met. The separation agreements also provided for extended vesting terms of certain options grants through the term of the consulting agreements. The Company recognized zero in incremental compensation cost for the year ended December 31, 2024, and $0.2 million in incremental compensation cost for the year ended December 31, 2023 in relation to the extended vesting terms.

10. Related Party Transactions

Relationship with GC Cell and GC Corp

GC Cell and GC Corp, subsidiaries of Green Cross Corp, are stockholders of the Company and are represented on the Company's board of directors.

In November 2019, October 2020, March 2021, and December 2022, the Company entered into a license agreement (collectively, the "License Agreements") with GC Cell (see Note 8). In August 2020, the Company entered into a Research and Service Agreement with GC Cell in which GC Cell is to provide mutually agreed research services in support of the research and development of one or more of the Selected Products that the Company has licensed from GC Cell under the License Agreements. The Company did not incur any research and development expense in connection with the agreements for the years ended December 31, 2024 and 2023. As of December 31, 2024 and December 31, 2023, the Company had no accounts payable and accrued expenses in connection with the GC Cell License Agreements and Research Service Agreement.

In September 2023, the Company and GC Cell amended the AB-201 Agreement (see Note 8). The Company recognized $0.3 million and $0.6 million of license and development support-related revenue for the years ended December 31, 2024 and 2023, respectively, on the statements of operations and comprehensive loss, related to GC Cell's achievement of a defined development milestone and development support activities under the Amended AB-201 Agreement. As of December 31, 2024 and December 31, 2023, total accounts receivable related to the Amended AB-201 Agreement were zero and $0.6 million, respectively.

Under the AB-205 Agreement, GC Cell agreed to reimburse the Company for Direct Costs incurred on behalf of GC Cell in accordance with the Development Plan under the AB-205 Agreement, provided that such reimbursed costs are deemed to form part of the Direct Costs incurred and paid by GC Cell (see Note 8). Total reimbursements for development costs invoiced to GC Cell in connection with the AB-205 Agreement were $0.1 million and $1.6 million for the years ended December 31, 2024 and 2023, respectively. During the years ended December 31, 2024 and 2023, the Company received payments from GC Cell in the amounts of $0.7 million and $1.0 million, respectively. As of December 31, 2024 and December 31, 2023, the Company had zero and $0.6 million recorded in the balance sheets as other receivables, respectively.

In March 2020, the Company entered into the Manufacturing Agreement with GC Cell, where GC Cell is to perform manufacturing services with respect to any biological or chemical product manufactured or to be manufactured for use in Phase 1 or Phase 2 clinical trials. The Company amended the Manufacturing Agreement in June 2020 to include the Company's right to terminate the agreement at will. For the years ended December 31, 2024 and 2023, the Company incurred $2.9 million and $3.7 million, respectively, in research and development expenses in connection with the agreement. As of December 31, 2024 and 2023, the Company had $1.0 million and $2.4 million, respectively, of accounts payable and accrued expenses in connection with the Manufacturing Agreement recorded in the balance sheets.

In January 2021, concurrent with entering into the Merck Collaboration Agreement, the Company also entered into a Partnered Program License Agreement with GC Cell to obtain exclusive, worldwide rights to GC Cell's CAR-NK technology with respect to the licensed products and to engage GC Cell to perform services in support of the research programs. The Company agreed to reimburse GC Cell for research and development services as these services were provided. The Company was required to pay GC Cell 100% of regulatory milestones, sales milestones and royalty payments received by Merck relating to products in Asia, Australia and New Zealand and 50% of upfront payments, license fees, regulatory milestones, sales milestones and royalty payments received by Merck relating to products in all other territories. In October 2023, the Merck Collaboration Agreement and development thereunder was terminated by Merck.

For the year ended December 31, 2023 the Company incurred $0.1 million related to research and development services in connection with the Partnered Program License Agreement.

Relationship with RA Capital

RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC—Series A (the "RA Capital Funds") are stockholders of the Company and a member of the Company's board of directors is affiliated with the RA Capital Funds.

In June 2024, the Company entered into a services agreement (the "Blackbird Services Agreement") with Blackbird Clinical, Inc. ("Blackbird"), an entity controlled by RA Capital Management, L.P. RA Capital Management, L.P. is the investment manager for the RA Capital Funds. Under the terms of the Blackbird Services Agreement, Blackbird provides consulting services in connection with the Company's clinical trials, including study strategy, clinical operations and patient operations. The Company incurred $0.3 million of research and development expenses in connection with the consulting services from Blackbird for the year ended December 31, 2024. No expenses were incurred with Blackbird for the year ended December 31, 2023. As of December 31, 2024, and December 31, 2023, the Company had $9 thousand and zero in accounts payable and accrued expenses, respectively, in connection with the Blackbird Services Agreement recorded in the balance sheets.

In November 2024, the Company entered into a services agreement (the "Carnot Services Agreement") with Carnot Pharma, LLC ("Carnot"), an entity controlled by RA Capital Management, L.P. RA Capital Management, L.P. is the investment manager for the RA Capital Funds. Under the terms of the Carnot Services Agreement, Carnot

provides consulting services in connection with the Company's clinical trials, including clinical operations and patient advocacy in support of the Company's AlloNK autoimmune programs. The Company incurred $15 thousand of research and development expenses in connection with the consulting services from Carnot for the year ended December 31, 2024. No expenses were incurred with Carnot for the year ended December 31, 2023. As of December 31, 2024, and December 31, 2023, the Company had $15 thousand and zero in accounts payable and accrued expenses, respectively, in connection with the Carnot Services Agreement recorded in the balance sheets.

11. Commitments and Contingencies

Operating Leases

The Company has multiple facility leases in San Diego, California, for office and laboratory space, including a cGMP manufacturing center, under non-cancellable operating leases with various expiration dates through 2029.

The Company leases certain office space in San Diego, California, under a non-cancelable operating lease, with a term through December 2025 (the "Executive Drive Lease"). The lease agreement for 13,405 square feet commenced on December 23, 2019, with a six-year initial term and includes aggregate monthly payments to the lessor of $2.8 million. The Executive Drive Lease also provides for rent abatements and scheduled increases in base rent. In connection with the lease, the Company made a one-time cash security deposit in the amount of $0.4 million, of which $0.2 million was refunded in October 2021, and the remaining $0.2 million is refundable at the end of the lease term and is included in other long-term assets in the Company's balance sheets. The Executive Drive Lease includes a renewal option, which includes an option to renew for five additional years. The Company will not exercise the option and, as such, is not reflected as part of the ROU asset and associated lease liabilities.

In June 2021, the Company entered into a lease agreement for 51,621 square feet of office and laboratory space, and a cGMP manufacturing center in San Diego, California (the "Morehouse Lease"), which represented a portion of a new facility that was under construction. The construction and design of the asset was the primary responsibility of the lessor. The Company was involved in certain aspects of construction and design for certain interior features and leasehold improvements that will be beneficial to the Company to better suit its business needs and intended purpose of the space. The Morehouse Lease is accounted for as an operating lease and commenced in the second quarter of 2022 (office and laboratory space) and in the third quarter 2022 (cGMP manufacturing center). The Morehouse Lease has an initial term of 88 months and includes aggregate monthly payments to the lessor of approximately $23.2 million with a rent escalation clause, and a tenant improvement allowance of approximately $12.3 million. The lease agreement required the Company to provide an unconditional and irrevocable letter of credit in the amount of $0.2 million, which is recorded as restricted cash on the Company's balance sheets as of December 31, 2024 and 2023.

In August 2022, the Company entered into a lease agreement to use designated laboratory and vivarium space in San Diego, California (the "Explora Lease"). The Explora Lease is accounted for as an operating lease and commenced in August 2022. The Explora Lease has an initial term of 36 months and includes aggregate monthly payments to the lessor of approximately $0.8 million with a rent escalation clause.

The following table presents operating rent expense and related short-term lease costs (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Rent expense	$ 4,052	$ 4,113
Variable lease expense	2,029	$ 2,329
Amount of rent expense related to short-term leases	—	286

Future minimum annual obligations under the Company's operating leases with terms in excess of one year are as follows (in thousands):

Year Ended December 31,	
2025	4,070
2026	3,529
2027	3,520
2028	3,626
2029	2,291
Total minimum lease payments	17,036
Less: amount representing interest	(2,848)
Present value of operating lease liabilities	14,188
Less: operating lease liabilities, current	(3,618)
Operating lease liabilities, net of current portion	$ 10,570

As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on average discount rate, which were as follows:

	AS OF	
	DECEMBER 31, 2024	DECEMBER 31, 2023
Weighted-average remaining lease term	4.4 years	5.3 years
Weighted-average discount rate	7.7%	7.8%

On July 22, 2022, the Company entered into a sublease (the "Sublease Agreement") with Origis Operating Services, LLC, (the "Sublessee"), whereby the Company agreed to sublease to Sublessee all of the 13,405 rentable square feet of office space in San Diego, California currently leased by the Company under the Executive Drive Lease. The sublease commenced on August 1, 2022, and has a term through December 31, 2025. The aggregate base rent is approximately $2.6 million commencing August 1, 2022. The Company records sublease income as a reduction of general and administrative expense.

The expected undiscounted cash flows to be received from the sublease are as follows (in thousands):

PERIOD ENDED DECEMBER 31,	
2025	$ 873
Total	$ 873

The Company recognized sublease income of $0.8 million for each of the years ended December 31, 2024 and 2023.

12. Income Taxes

The Company reported pre-tax book losses in the United States of $65.4 million and $28.7 million, for the years ended December 31, 2024 and 2023, respectively.

A reconciliation of the U.S. federal statutory income tax rate to the effective tax rate is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Expected tax benefit at statutory rate	$ (13,730)	$ (6,033)
State income tax, net of federal benefit	(3,531)	(1,024)
Permanent and other	272	118
Change in fair value of SAFEs	755	—
Stock-based compensation expense	(1,479)	1,109
Executive compensation expense	1,626	—
Research credits, net	(2,794)	(3,106)
Change in state and local tax rate	—	(2,335)
Change in valuation allowance	18,881	11,343
Provision for income taxes	$ —	$ 72

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets and liabilities consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Net operating loss carryforwards	$ 29,693	$ 20,424
Capitalized research and development	21,731	16,407
Operating lease liabilities	3,970	4,733
Intangible assets	959	1,042
Research and development credits	8,423	5,652
Other, net	3,410	2,121
Total deferred tax assets	$ 68,186	$ 50,379
Valuation allowance	(63,115)	(44,112)
Deferred tax assets, net of valuation allowance	$ 5,071	$ 6,267
Deferred tax liabilities:		
Fixed assets	(1,211)	(1,636)
Operating lease assets	(3,860)	(4,631)
Total deferred tax liabilities	$ (5,071)	$ (6,267)
Net deferred tax assets / (liabilities)	$ —	$ —

The Company increased its valuation allowance by $19.0 million for the year ended December 31, 2024 in order to maintain a full valuation allowance against its deferred tax assets. Due to the Company's cumulative losses since inception, the Company recorded a full valuation allowance against its deferred tax assets as of December 31, 2024. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

The Company has net operating loss ("NOL") carryforwards for federal and state income tax purposes of $99.7 million and $143.4 million, respectively, as of December 31, 2024. All of the federal net operating loss carryforwards are not subject to expiration but are limited to 80% of the taxable income in the year the carryforward is used. The state net operating loss carryforwards, if not utilized, will expire in 2039.

As of December 31, 2024, the Company has federal and state research and development credit carryforwards of $7.4 million and $5.2 million, respectively. The federal credits will expire in 2041 and the state credits are available indefinitely.

Pursuant to Sections 382 and 383 of the Code, and corresponding provisions of state law, annual use of the Company's federal and state NOLs and research and development credit carryforwards may be limited in the event

of a cumulative ownership change of more than 50 percentage points (by value) within a rolling three-year period. The Company has not completed an ownership change analysis pursuant to Section 382. If ownership changes have occurred or occurs in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance.

The Company files income tax returns in the United States federal jurisdiction and California. The Company is not currently under examination by any federal, state or local tax authority and all tax years from inception remain open to United States federal and state examination to the extent of the utilization of net operating loss and credit carryovers.

As of December 31, 2024, the Company had unrecognized tax benefits of $5.0 million related primarily to the federal and state research and development credits as a result of no formal research credit study performed.

A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Unrecognized Tax Benefits - Beginning	$ 3,999	$ 2,853
Increases related to current year positions	1,012	1,040
Increases (decreases) related to prior year positions	(16)	106
Unrecognized Tax Benefits - Ending	$ 4,995	$ 3,999

Due to the full valuation allowance, future recognition of previously unrecognized tax benefits will not impact the Company's effective tax rate. The Company recognizes interest expense and penalties related to the above unrecognized tax benefits within income tax expense (benefit). Management determined that no accrual for interest and penalties was required as of December 31, 2024.

13. Segment Information

The CODM assesses performance for the life sciences segment based on net loss, which includes evaluating the progress of ongoing clinical trials. The life sciences segment is dedicated to developing off-the-shelf, allogeneic, NK cell-based therapies that are effective, safe and accessible for patients with devastating autoimmune diseases and cancers. The measure of segment assets is reported on the balance sheet as total assets. All long-lived assets are maintained in the United States. The following table contains information on segment profit or loss, including significant segment expenses (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Revenue	$ 251	$ 33,492
Less:		
AB-101	19,978	14,090
Other programs[(a)]	330	3,797
Personnel-related	30,465	28,610
Other[(b)]	16,760	17,666
Other income, net	1,909	2,023
Provision for income taxes	—	(72)
Net loss	$ (65,373)	$ (28,720)

(a)Other programs primarily includes costs associated with AB-201, Merck, and Affimed.

(b)Other primarily includes consultant, depreciation, rent, common area maintenance, lab supplies, legal, and insurance expenses.